Risks of Bromethalin Use to Federally Threatened Alameda Whipsnake (*Masticophis lateralis euryxanthus*) and the Federally Endangered Salt Marsh Harvest Mouse (*Reithrodontomys raviventris*)

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List of Commonly Used Abbreviations and Nomenclature

µg/kg	Symbol for “micrograms per kilogram”
µg/L	Symbol for “micrograms per liter”
ºC	Symbol for “degrees Celsius”
AAPCO	Association of American Pesticide Control Officials
a.i.	Active Ingredient
AIMS	Avian Monitoring Information System
Acc#	Accession Number
amu	Atomic Mass Unit
AW	Alameda whipsnake
BCF	Bioconcentration Factor
BEAD	Biological and Economic Analysis Division
bw	Body Weight
CAM	Chemical Application Method
CARB	California Air Resources Board
CBD	Center for Biological Diversity
CDPR	California Department of Pesticide Regulation
CDPR-PUR	California Department of Pesticide Regulation Pesticide Use Reporting Database
CI	Confidence Interval
CL	Confidence Limit
EC	Emulsifiable Concentrate
EC_{05}	5% Effect Concentration
EC_{25}	25% Effect Concentration
EC_{50}	50% (or Median) Effect Concentration
ECOTOX	EPA managed database of Ecotoxicology data
EEC	Estimated Environmental Concentration
EFED	Environmental Fate and Effects Division
e.g.	Latin *exempli gratia* (“for example”)
EIM	Environmental Information Management System
EPI	Estimation Programs Interface
ESU	Evolutionarily significant unit
et al.	Latin *et alii* (“and others”)
etc.	Latin *et cetera* (“and the rest” or “and so forth”)
EXAMS	Exposure Analysis Modeling System

FIFRA	Federal Insecticide Fungicide and Rodenticide Act
FQPA	Food Quality Protection Act
ft	Feet
GENEEC	Generic Estimated Exposure Concentration model
HPLC	High Pressure Liquid Chromatography
IC_{05}	5% Inhibition Concentration
IC_{50}	50% (or median) Inhibition Concentration
i.e.	Latin for *id est* ("that is")
IECV1.1	Individual Effect Chance Model Version 1.1
KABAM	K_{OW} (based) Aquatic BioAccumulation Model
kg	Kilogram(s)
kJ/mole	Kilojoules per mole
km	Kilometer(s)
K_{AW}	Air-water Partition Coefficient
Kd	Solid-water Distribution Coefficient
KF	Freundlich Solid-Water Distribution Coefficient
K_{OC}	Organic-carbon Partition Coefficient
K_{OW}	Octanol–water Partition Coefficient
LAA	Likely to Adversely Affect
lb a.i./A	Pound(s) of active ingredient per acre
LC_{50}	50% (or Median) Lethal Concentration
LD_{50}	50% (or Median) Lethal Dose
LOAEC	Lowest Observable Adverse Effect Concentration
LOAEL	Lowest Observable Adverse Effect Level
LOC	Level of Concern
LOD	Level of Detection
LOEC	Lowest Observable Effect Concentration
LOQ	Level of Quantitation
m	Meter(s)
MA	May Affect
MATC	Maximum Acceptable Toxicant Concentration
m^2/day	Square Meters per Days
ME	Microencapsulated
mg	Milligram(s)
mg/kg	Milligrams per kilogram (equivalent to ppm)
mg/L	Milligrams per liter (equivalent to ppm)

mi	Mile(s)
mmHg	Millimeter of mercury
MRID	Master Record Identification Number
MW	Molecular Weight
n/a	Not applicable
NASS	National Agricultural Statistics Service
NAWQA	National Water Quality Assessment
NCOD	National Contaminant Occurrence Database
NE	No Effect
NLAA	Not Likely to Adversely Affect
NLCD	National Land Cover Dataset
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NOAEC	No Observable Adverse Effect Concentration
NOAEL	No Observable Adverse Effect Level
NOEC	No Observable Effect Concentration
NRCS	Natural Resources Conservation Service
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides and Toxic Substances
ORD	Office of Research and Development
PCE	Primary Constituent Element
pH	Symbol for the negative logarithm of the hydrogen ion activity in an aqueous solution, dimensionless
pKa	Symbol for the negative logarithm of the acid dissociation constant, dimensionless
ppb	Parts per Billion (equivalent to µg/L or µg/kg)
ppm	Parts per Million (equivalent to mg/L or mg/kg)
PRD	Pesticide Re-Evaluation Division
PRZM	Pesticide Root Zone Model
ROW	Right of Way
RQ	Risk Quotient
SLN	Special Local Need
SMHM	Salt Marsh Harvest Mouse
TG	Tidewater Goby
T-HERPS	Terrestrial Herpetofaunal Exposure Residue Program Simulation
T-REX	Terrestrial Residue Exposure Model

UCL	Upper Confidence Limit
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WP	Wettable Powder
wt	Weight

1. Executive Summary

1.1. Purpose of Assessment

The purpose of this assessment is to evaluate potential direct and indirect effects on the federally threatened Alameda whipsnake (AW, *Masticophis lateralis euryxanthus*) and the federally endangered salt marsh harvest mouse (SMHM, *Reithrodontomys ravivertis*) arising from FIFRA regulatory actions regarding use of bromethalin on agricultural and non-agricultural sites. In addition, this assessment evaluates whether these actions can be expected to result in modification of designated critical habitat for the AW. This assessment was completed in accordance with the U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS) *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998), procedures outlined in the Agency's Overview Document (USEPA, 2004), and consistent with a suit in which bromethalin was alleged to be of concern to the AW and SMHM (*Center for Biological Diversity (CBD) vs. EPA et al*. (Case No. 07-2794-JCS)).

Bromethalin is a neurotoxic vertebrate control agent. The mode of action is uncoupling of mitochondrial oxidative phosphorylation, which leads to fluid build-up and demethylination inside the central nervous system, and eventually to respiratory failure. Bromethalin is the active ingredient of various bait products registered for the use to control commensal rodents (rats and mice) and moles. The rodent-control baits are formulated in pellets or tablets, which are typically placed in bait stations[1], or in weather-resistant blocks. For mole control, bait is placed within the mole's underground runways.

The AW, a subspecies of the California whipsnake (*Masticophis lateralis*), was listed as threatened in 1997 by the USFWS. A recovery plan for this and other threatened and endangered species of the chaparral and scrub community east of San Francisco Bay, California was approved by the USFWS in 2003. Critical habitat was designated for this subspecies in 2006. The subspecies occurs in the Inner Coast Ranges in Contra Costa, Alameda, San Joaquin, and Santa Clara Counties in California.

The SMHM was listed as an endangered species by the USFWS in 1970. A recovery plan for the SMHM was approved by the USFWS in 1973. No critical habitat has been designated for this species. The species is composed of two subspecies, the more northern *R. r. halicoetes* and the more southern *R .r. raviventris*. It is found in tidal and non-tidal salt marshes along the San Francisco, San Pablo, and Suisun Bays in California.

[1] The Risk Mitigation Decision for Ten Rodenticides, which was issued in May 2008 and revised in June 2008, requires labels of all bromethalin rodenticide bait products sold after June 4, 2011 to mandate that all outdoor placement of bait be within weather-resistant bait stations. However, not all labels of bromethalin rodenticide products were in compliance with this requirement at the time this assessment was completed.

1.2. Scope of Assessment

1.2.1. Uses Assessed

Bromethalin is a rodenticide that is used in various bait products for control of pest species of rats, mice, and moles. Registered formulation types include bait pellets, bait blocks, and packages containing granular bait. For mole control, bromethalin is also formulated as impregnated material designed to mimic grubs and worms. Baits are often, but not always, placed inside of bait boxes. Currently, labeled use sites of bromethalin products used for rodent control include in and around buildings (placement must be within 50 feet of exterior walls), inside transport vehicles (ships, trains, and aircraft), alleys in urban areas, and sewers. Buildings where bromethalin bait may be used include residential, commercial, industrial, and agricultural premises, as well as port and terminal buildings. Labeled uses sites of bromethalin products used for mole control include residential lawns, ornamental gardens, recreation areas, golf courses, nurseries, and other nonagricultural uncultivated areas. Bait used for mole control may be applied only in underground runways of moles. All of these uses are considered as part of the Federal action evaluated in this assessment.

1.2.2. Environmental Chemistry, Fate and Transport, and Physicochemical Properties of Bromethalin

Chemical information and physicochemical properties of bromethalin are summarized in Table 2-1 in Section 2.4.1. These data were taken from the Footprint Pesticide Environmental Fate Properties Database (University of Hamfordshire, 2010) because no chemical property data have been submitted to the Agency. These data are presented for information purposes only; table values are not used quantitatively in this assessment.

1.2.3. Evaluation of Degradates and Stressors of Concern

The major degradate detected in the aerobic soil metabolism study, desnitrobromethalin, comprising 43% of the applied, also appears to be persistent. The toxicity and mobility of this degradate is unknown. Leaching of the active ingredient from the bait into rainwater is expected to be minimal, resulting in negligible contamination of soil and water (see Section 2.10.1.a). The exposure to nontarget organisms is expected to be limited to exposure to the toxicant in the intact bait. Therefore, the formation of this degradate in soil was not considered in this assessment.

Bromethalin is transformed into the metabolite desmethylbromethalin in mammals. This metabolite is more toxicologically active than the parent (Van Lier and Cherry, 1988). Because this transformation would occur in the animals tested in the laboratory to a similar degree as in animals exposed in the wild, any additional toxicity caused by this transformation would be reflected by the toxicity data and thus is taken into account in the assessment of risk. There is no evidence that desmethylbromethalin forms in significant quantities in the environment.

1.3. Assessment Procedures

A description of routine procedures for evaluating risk to the San Francisco Bay Species is provided in Attachment I.

1.3.1. Exposure Assessment

1.3.1.a. Aquatic Exposures

As bromethalin is used only in bait products and in used in very small quantities, it is probable that contact of this chemical with water will be minimal. The only aquatic species that are relevant to this assessment are aquatic plants for indirect effects to the SMHM and no aquatic plant toxicity data are available. Concentrations of bromethalin in both freshwater and saltwater marshes are expected to be negligible and not impact aquatic vegetation. Models that estimate concentrations in surface water or calculate spray drift deposition of bromethalin on aquatic habitats were therefore not needed (see Section 2.10.1.a). No surface water monitoring data are available for bromethalin.

1.3.1.b. Terrestrial Exposures

Bromethalin exposures to terrestrial species resulting from application of bromethalin baits were evaluated by assuming species directly consumed baits of various types. Since primary exposure takes place by direct consumption of baits, no terrestrial exposure model needed to be employed. The concentration of active ingredient in food was assumed simply to be the concentration of AI in the bait. The Agency does not have an approved standard method of predicting secondary exposure from terrestrial animals that eat other animals which have ingested bait. As a tier 1 risk assessment, the amount of active ingredient ingested by the AW from secondary exposure was assumed to be equal to the amount of active ingredient that a prey item would ingest if it consumed bromethalin bait at its daily ingestion rate. The prey was assumed to be a house mouse, mole, or Norway rat, and the amount of bait these species ingested was assumed based on their body weights. The weights of these species were assumed to be the maximums of the reported body weight ranges to maximize secondary exposure to the AW. All of the bromethalin ingested by the prey was assumed to be available to and assimilated by the AW that eats it.

1.3.2. Toxicity Assessment

The assessment endpoints include direct toxic effects on survival, reproduction, and growth of individuals, as well as indirect effects, such as reduction of the food source and/or modification of habitat. Federally-designated critical habitat has been established for the AW. Primary constituent elements (PCEs) were used to evaluate whether bromethalin has the potential to modify designated critical habitat. The Agency evaluated registrant-submitted studies and data from the open literature to characterize bromethalin toxicity. The assessment used the most sensitive toxicity value available from acceptable or supplemental studies for each taxon relevant for estimating potential risks to the assessed species and/or their designated critical habitat.

Section 4 summarizes the ecotoxicity data available on bromethalin. Bromethalin is *very highly toxic* to birds on both an acute oral and a subacute dietary exposure basis, and is *very highly toxic* to mammals on an acute oral exposure basis. No data are available to assess the chronic toxicity of bromethalin to birds. For mammals, chronic exposure has been found to cause significant maternal toxicity at dietary concentrations of 8.25 mg ai/kg-diet in the rabbit and 10 mg ai/kg-diet in the rat. Chronic NOAEC values were established at 3.3 mg ai/kg-diet for the rabbit and 6 mg ai/kg-diet for the rat. No data are available on the toxicity of bromethalin to terrestrial invertebrates or to terrestrial plants.

1.3.3. Measures of Risk

Acute and chronic risk quotients (RQs) are compared to the Agency's Levels of Concern (LOCs) to identify instances where bromethalin use has the potential to adversely affect the assessed species or adversely modify their designated critical habitat. When RQs for a particular type of effect are below LOCs, the pesticide is considered to have "no effect" on the species and its designated critical habitat. Where RQs exceed LOCs, a potential to cause adverse effects or habitat modification is identified, leading to a conclusion of *May Affect*. If bromethalin use "may affect" the assessed species, and/or may cause effects to designated critical habitat, the best available additional information is considered to refine the potential for exposure and effects, and distinguish actions that are *Not Likely to Adversely Affect* (NLAA) from those that are *Likely to Adversely Affect* (LAA).

1.4. Summary of Conclusions

Based on the best available information, the Agency makes a ***May Affect*** and a ***Likely to Adversely Affect*** determination for the use of bromethalin relative to both the AW and the SMHM. Additionally, the Agency has determined use of bromethalin has the potential to cause modification of the designated critical habitat of the AW from the use of the chemical. (Critical habitat has not been designated for the SMHM.) Given the LAA determination for the AW and the SMHM, and potential modification of designated critical habitat for the AW, a description of the baseline status and cumulative effects is provided in Attachment III.

Table 1-1. Effects Determination Summary for Effects of Bromethalin on the Alameda Whipsnake and the Salt Marsh Harvest Mouse

Species	Effects Determination	Basis for Determination
Alameda whipsnake (*Masticophis lateralis euryxanthus*)	*May Affect* and *Likely to Adversely Affect* (LAA)	**Potential for Direct Effects**
		Risk assessment indicates use of bromethalin potentially will result in direct effects to the AW from acute toxicity. Dietary exposure estimates and acute toxicity to reptiles (based on acute toxicity data for birds) result in acute RQs that exceed the LOC for both primary and secondary exposure. While adverse acute effects are possible for both primary and secondary exposure, secondary exposure is considered the primary threat to this species. Data were not available to assess chronic toxicity; however, since risk is predicted for acute exposure based on mortality, and sublethal effects were observed with sublethal acute exposure, risk of chronic effects is also assumed.

Species	Effects Determination	Basis for Determination
		Potential for Indirect Effects
		Terrestrial prey items Risk assessment indicates use of bromethalin will likely reduce the abundance of terrestrial vertebrates which serve as prey for this species. This conclusion is based on acute RQs for birds, and acute and chronic RQs for mammals, which exceed the LOC. ***Habitat Modifications*** Risk assessment indicates use of bromethalin may adversely modify the habitat of this species by reducing the availability of small mammal burrows. This conclusion is based on acute and chronic RQs for mammals that exceed the LOC.
Salt marsh harvest mouse (*Reithrodontomys ravivertis*)	*May Affect* and *Likely to Adversely Affect* (LAA)	**Potential for Direct Effects**
		Risk assessment indicates use of bromethalin will likely result in direct effects to the SMHM from acute and chronic toxicity. Dietary exposure estimates and data on acute and chronic toxicity to small mammals result in acute RQs that exceed the LOC for primary exposure. This species is predicted to be susceptible to primary exposure through direct contact with bromethalin bait products. This contact may result in ingestion of the bait, which would likely result in acute and chronic toxic effects.
		Potential for Indirect Effects
		Habitat Modifications Risk assessment indicates use of bromethalin may adversely modify the habitat of this species by reducing the availability of nest sites. This conclusion is based on acute RQs for birds and mammals, and acute and chronic RQs for mammals, that exceed the LOC. Adverse effects to birds and mammals may result in a reduction of abandoned bird and mammal nests, which are used as nest sites by this species.

Table 1-2. Effects Determination Summary for the Critical Habitat Impact Analysis

Designated Critical Habitat for:	Effects Determination	Basis for Determination
Alameda whipsnake (*Masticophis lateralis euryxanthus*)	Habitat Modification	Risk assessment indicates use of bromethalin may adversely modify the critical habitat of this species by reducing the availability of small mammal burrows. This may result in modification of PCE 3: "Lands containing rock outcrops, talus, and small mammal burrows within or adjacent to PCE 1 and or PCE 2." In addition, the availability of prey may be reduced in the critical habitat by toxicity to small birds, mammals, reptiles, and terrestrial-phase amphibians.

Table 1-3. Use Specific Summary of the Potential for Adverse Effects by Taxa.

Uses	Potential for Effects to Identified Taxa Found in the Terrestrial Environment

	SMHM and Small Mammals[1]		AW and Reptiles[2]		Small Birds[3]		Amphibians[4]	
	Acute	**Chronic**	**Acute**	**Chronic**	**Acute**	**Chronic**	**Acute**	**Chronic**
Rodent Control	Yes	Yes	Yes	Yes[5]	Yes	Yes[5]	Yes	Yes[5]
Mole Control	Yes	Yes	Yes	Yes[5]	Yes	Yes[5]	Yes	Yes[5]

1 A yes in this column indicates a potential for direct effects to the SMHM and indirect effects to the AW.
2 A yes in this column indicates the potential for direct and indirect effects to the AW.
3 A yes in this column indicates a potential for indirect effects to the SMHM and the AW.
4 A yes in this column indicates a potential for the AW.
5 Chronic toxicity data are not available to assess this species, but chronic risk may be assumed based upon the high acute risks.

Based on the conclusions of this assessment, a formal consultation with the U. S. Fish and Wildlife Service under Section 7 of the Endangered Species Act should be initiated.
When evaluating the significance of this risk assessment's direct/indirect and adverse habitat modification effects determinations, it is important to note that pesticide exposures and predicted risks to the species and its resources (*i.e*., food and habitat) are not expected to be uniform across the action area. Bromethalin exposure and associated risks to the species and its resources are expected to rapidly decrease with increasing distance away from the sites of bait placement. Evaluation of the implication of this non-uniform distribution of risk to the species would require information and assessment techniques that are not currently available. Examples of such information and methodology required for this type of analysis would include the following:

- Enhanced information on the density and distribution of AW and SMHM within the action area and/or applicable designated critical habitat. This information would allow for quantitative extrapolation of the present risk assessment's predictions of individual effects to the proportion of the population extant within geographical areas where those effects are predicted. Furthermore, such population information would allow for a more comprehensive evaluation of the significance of potential resource impairment to individuals of the assessed species.
- Quantitative information on prey base requirements for the assessed species. While existing information provides a preliminary picture of the types of food sources utilized by the assessed species, it does not establish minimal requirements to sustain healthy individuals at varying life stages. Such information could be used to establish biologically relevant thresholds of effects on the prey base, and ultimately establish geographical limits to those effects. This information could be used together with the density data discussed above to characterize the likelihood of adverse effects to individuals.
- Information on population responses of prey base organisms to the pesticide. Currently, methodologies are limited to predicting exposures and likely levels of direct mortality, growth or reproductive impairment immediately following exposure to the pesticide. The degree to which repeated exposure events and the inherent demographic characteristics of the prey population play into the extent to which prey resources may recover is not predictable. An enhanced understanding of long-term prey responses to pesticide exposure would allow for a more refined determination of

the magnitude and duration of resource impairment, and together with the information described above, a more complete prediction of effects to individual species and potential modification to critical habitat.

2. Problem Formulation

Problem formulation provides a strategic framework for the risk assessment. By identifying the important components of the problem, it focuses the assessment on the most relevant life history stages, habitat components, chemical properties, exposure routes, and endpoints. The structure of this risk assessment is based on guidance contained in U.S. EPA's *Guidance for Ecological Risk Assessment* (USEPA, 1998a), the Services' *Endangered Species Consultation Handbook* (USFWS/NMFS, 1998) and is consistent with procedures and methodology outlined in the Overview Document (USEPA, 2004a) and reviewed by the U.S. Fish and Wildlife Service and National Marine Fisheries Service (USFWS/NMFS/NOAA, 2004).

2.1. Purpose

The purpose of this endangered species assessment is to evaluate potential direct and indirect effects on individuals of the federally threatened AW and the federally endangered SMHM arising from FIFRA regulatory actions regarding use of bromethalin for rodent control. This ecological risk assessment has been prepared consistent with a stipulated injunction in the case *Center for Biological Diversity (CBD) vs. EPA et al*. (Case No. 07-2794-JCS) entered in Federal District Court for the Northern District of California on May 17, 2010.

In this assessment, direct and indirect effects to the AW and SMHM and potential modification to designated critical habitat for the AW are evaluated in accordance with the methods described in the Agency's Overview Document (USEPA, 2004).

The AW, a subspecies of the California whipsnake (*Masticophis lateralis*), was listed as threatened in 1997 by the USFWS. A recovery plan for this and other threatened and endangered species of the chaparral and scrub community east of San Francisco Bay, California was approved by the USFWS in 2003. Critical habitat was designated for this subspecies in 2006. The subspecies occurs in the Inner Coast Ranges in Contra Costa, Alameda, San Joaquin, and Santa Clara Counties in California.

The SMHM was listed as an endangered species by the USFWS in 1970. A recovery plan for the SMHM was approved by the USFWS in 1973. No critical habitat has been designated for this species. The SMHM is composed of two subspecies, the more northern *R. r. halicoetes* and the more southern *R .r. raviventris*. This species is found in tidal and non-tidal salt marshes along the San Francisco, San Pablo, and Suisun Bays in California. *R. r. halicoetes* occurs mainly in marshes bordering the San Pablo and Suisun Bays in Contra Costa, Solano, Napa, Sonoma and Marin Counties. *R .r. raviventris* occurs in marshes bordering the San Francisco Bay in San Mateo, Alameda, and Santa Clara Counties.

In accordance with the Overview Document, provisions of the ESA, and the Services' *Endangered Species Consultation Handbook*, the assessment of effects associated with registrations of bromethalin is based on an action area. The action area is the area directly or indirectly affected by the federal action, as indicated by the exceedance of the Agency's Levels of Concern (LOCs). It is acknowledged that the action area for a national-level FIFRA regulatory decision associated with a use of bromethalin may potentially involve numerous areas throughout the United States and its Territories. However, for the purposes of this assessment, attention will be focused on relevant sections of the action area including those geographic areas associated with locations of the AW and SMHM and their designated critical habitat within the state of California. As part of the "effects determination," one of the following three conclusions will be reached separately for each of the assessed species in the lawsuits regarding the potential use of bromethalin in accordance with current labels:

- "No effect";
- "May affect, but not likely to adversely affect"; or
- "May affect and likely to adversely affect".

Additionally, for habitat and PCEs, a "No Effect" or a "Habitat Modification" determination is made.

A description of routine procedures for evaluating risk to the San Francisco Bay Species is provided in Attachment I. Not all of the methods described in Attachment I are relevant to this risk assessment.

2.2. Scope

The end result of the EPA pesticide registration process (*i.e.*, the FIFRA regulatory action) is an approved product label. The label is a legal document that stipulates how and where a given pesticide may be used. Product labels (also known as end-use labels) describe the formulation type (*e.g.*, liquid or granular), acceptable methods of application, approved use sites, and any restrictions on how applications may be conducted. Thus, the use or potential use of bromethalin in accordance with the approved product labels for California is "the action" relevant to this ecological risk assessment.

In California, bromethalin is registered for use in baits to control rodents and moles. It is registered for use for controlling three commensal rodents, the Norway rat (*Rattus norvegigus*), the roof rat (*Rattus rattus*), and the house mouse (*Mus musculus*), and various moles. The mole species occurring in this region of California for which bromethalin bait may be used is the broad-footed mole (*Scapanus latimanus*). Products containing bromethalin are registered for use for rodent control in and around buildings, inside transport and cargo vehicles, in urban alleys, and in sewers. For mole control, a single product is registered for use in various nonagricultural areas, including lawns, golf courses, and ornamental gardens.

Although current registrations of bromethalin allow for use nationwide, this ecological risk assessment and effects determination addresses currently registered uses of bromethalin in portions of the action area that are reasonably assumed to be biologically relevant to the AW and

SMHM, and the designated critical habitat for the AW. Further discussion of the action areas for these species is provided in Section 2.7.

2.2.1. Evaluation of Degradates

This risk assessment evaluates the risk of exposure to parent bromethalin alone. It does not attempt to evaluate the risk posed by environmental degradation products of bromethalin. Risk from exposure to degradation products was not considered a major concern because the majority of risk is expected to be from acute exposure from direct consumption of the intact bait products, or from secondary exposure from consumption of prey which feed on the intact bait. Contamination of soil and water from use of the bait products is expected to be minimal. Therefore, formation of degradation products in the soil and water was not a major concern in this assessment.

In the rat, demethylation of bromethalin converts the parent compound into desmethylbromethalin. Desmethylbromethalin has been found to be an extremely potent uncoupler of oxidative phosphorylation, and believed to be the "activated" form of this compound which is responsible for most of the neurotoxicity of bromethalin in mammals (Van Lier and Cherry, 1988). This metabolic activation of bromethalin is expected to occur in the test animals dosed in the laboratory toxicity studies similarly to the way it occurs in wild animals. Therefore, the toxicity resulting from metabolic transformation in animals is accounted for in the laboratory toxicity data generated, and thus also in this risk assessment which is based on those toxicity data.

2.2.2. Evaluation of Mixtures

The Agency does not routinely include, in its risk assessments, an evaluation of mixtures of active ingredients, either those mixtures of multiple active ingredients in product formulations or those in the applicator's tank. In the case of the product formulations of active ingredients (that is, a registered product containing more than one active ingredient), each active ingredient is subject to an individual risk assessment for regulatory decision regarding the active ingredient on a particular use site. If effects data are available for a formulated product containing more than one active ingredient, they may be used qualitatively or quantitatively in accordance with the Agency's Overview Document and the Services' Evaluation Memorandum (USEPA, 2004; USFWS/NMFS/NOAA, 2004).

Bromethalin does not have registered products that contain multiple active ingredients. All registered products of bromethalin are baits which contain only bromethalin as an active ingredient.

2.3. Previous Assessments

Reregistration Eligibility Decision

The Agency assessed the risks of rodenticide uses of bromethalin, along with seven other rodenticides, in the *Reregistration Eligibility Decision (RED): Rodenticide Cluster* that was

published in 1998 (USEPA, 1998b). This document included an ecological effects risk assessment that was based on environmental fate and ecotoxicological studies that had been submitted by the registrants of bromethalin at that time. The assessment concluded that use of bromethalin would pose a risk to small mammals that may feed on the bait. However, risk to birds from primary exposure was characterized as minimal. Direct exposure of birds to bromethalin bait was judged to be minimal because it was used exclusively in and around buildings or sewers, and because label restrictions required baits to be contained in protected bait stations or otherwise made inaccessible to nontarget wildlife. (It should be noted, however, that this risk assessment did not include use for mole control, which was not registered by the EPA until 2004, after the RED was published.) Secondary risk to wildlife was not assessed because secondary toxicity data were not available. It was noted, however, that the Agency's incident database contained no records of wildlife being killed from feeding on rodents poisoned by bromethalin. Despite being highly toxic to aquatic animals, risk to all aquatic organisms was presumed to be minimal because the registered use patterns were judged unlikely to result in significant contamination of aquatic environments. Even for use in sewers, where some potential contact with water was possible, little bromethalin was expected to be released from the bait into water because the water solubility of bromethalin is very low (2 µg/L), and bait products used in sewers are formulated in weather-resistant paraffinized blocks. The maximum application rate in sewers is extremely small (0.0000375 pounds per placement). No data were available to assess risk of bromethalin to plants or insects.

Rodenticide Comparative Assessment

An assessment of the risks of bromethalin to terrestrial wildlife was also included in the 2004 assessment *Potential Risks of Nine Rodenticides to Birds and nontarget Mammals: a Comparative Approach*. Bromethalin was found to be more toxic to birds than first-generation anticoagulant rodenticides, but less toxic than second-generation anticoagulant rodenticides and zinc phosphide. When exposure as well as toxicity was analyzed, the risk to birds from primary exposure was found to be significantly less than for brodifacoum, difenthialone, and zinc phosphide, but comparable to the other 7 rodenticides evaluated. For nontarget mammals, a comparative analysis found bromethalin posed much less risk from primary exposure than zinc phosphide, and somewhat less risk than brodifacoum, bromadialone, warfarin, difethialone, and diphacinone. Risk of bromethalin was comparable to the other rodenticides evaluated.

Risk to wildlife from secondary exposure to bromethalin could not be fully evaluated because no data were available on the liver retention time of bromethalin, and no secondary mortality data were available for birds. However, a laboratory study with dogs found no mortality from secondary exposure (van Lier, 1981). In addition, field studies and wildlife monitoring studies have not identified bromethalin as a widespread contaminant in the tissue of wildlife as has been found with many of the anticoagulant rodenticides, especially brodifacoum and bromadiolone. Finally, no wildlife mortality incident was linked to bromethalin, whereas numerous mortality incidents have been linked to the common anticoagulant rodenticides. This assessment therefore concluded that bromethalin poses less secondary risk to wildlife than anticoagulant rodenticides.

Biological Opinion on the Salt Marsh Harvest Mouse

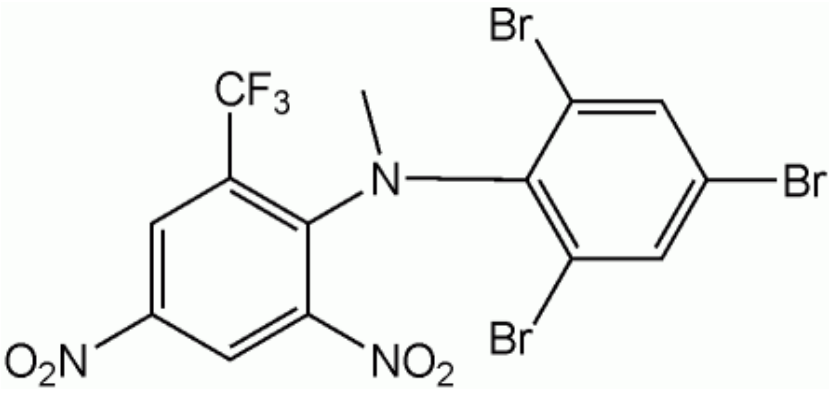
The U.S. Fish and Wildlife Service (Service) addressed the risk of bromethalin use on the SWHM in a Biological Opinion (BO) issued in March of 1993. The Service produced the BO in response to a 1991 request by the Environmental Protection Agency for formal consultation on 16 registered vertebrate pest agents. The BO opinion included an evaluation of the use of bromethalin in and around buildings to control the Norway rat, roof rat, and house mouse, and the potential for such uses to jeopardize the continued existence of the salt marsh harvest mouse. Being highly toxic to mammals, bromethalin was considered to be a threat to listed rodents which may inhabit areas adjacent to buildings where bromethalin may be used and may be attracted to rodenticide bait. The risk from bromethalin was thought to be from the potential of direct consumption of bait, but not from secondary poisoning. The service determined that the SWHM was vulnerable to exposure to bait containing bromethalin because this species occupies areas with high human activity in which buildings would likely exist adjacent to their habitats. In addition, the Service thought that the restricted and highly fragmented nature of the habitat of this species increases both the risk of exposure to and the consequence of possible adverse effects from bromethalin. The Service therefore concluded that bromethalin use within the range of the SWHM is likely to jeopardize the existence of this species. They also concluded that prohibiting outdoor use of bromethalin within 100 yards of habitats occupied by this species would be a reasonable and prudent alternative to avoid jeopardy to the SWHM.

Considering this opinion by the Service, the current assessment revisits the risk assessment to the SWHM to determine the presumed risk using current risk assessment methodology. In addition, the current assessment takes into account any changes that were made in the labels of bromethalin products since the BO was issued in 1993, as well as any toxicity data that have become available since that time.

2.4. Environmental Fate Properties

2.4.1. Environmental Fate Characterization

Bromethalin Chemical Structure



Bromethalin Chemical name (IUPAC): 2,4,6-Tribromo-N-methyl-N-(2,4-dinitro- 6-trifluoromethylphenyl)aniline

The summary of chemical information and physicochemical properties of Bromethalin in Table 2-1 is taken from the European Union's Footprint database (University of Hamfordshire, 2010) due to lack of submitted data. The data in this table are presented for information purposes only; the studies from which these values were obtained were not available for evaluation, and, thus, the values are taken at face value. Therefore, the table values are not used qualitatively in this assessment.

Table 2-1. Summary of Chemical Information and Physicochemical Properties of Bromethalin

Mode of Action:	Toxin attacking central nervous system
Chemical Formula:	$C_{14}H_7Br_3F_3N_3O_4$
Smiles Code:	CN(C1=C(C=C(C=C1C(F)(F)F)[N+](=O)[O-])[N+](=O)[O-])C2=C(C=C(C=C2Br)Br)Br
CAS No.:	63333-35-7
Physical State:	Pale yellow crystals
Molecular Weight (g/mol):	577.9
Solubility - In water at 20ºC (mg l^{-1}):	0.002
Bulk density (g ml-1)/Specific gravity:	1.36
Octanol-water partition coefficient at pH 7, 20^{o}C:	4.79×10^{7}
Flash Point (^{o}C):	Not highly flammable
Boiling Point (^{o}C):	Decomposes before boiling
Melting Point: (^{o}C):	151
Vapor pressure at 25^{o}C (mPa):	0.013
Henry's law constant at 25^{o}C (Pa m3 mol^{-1}):	4.08×10^{-04}
Henry's law constant at 20^{o}C (dimensionless):	1.54×10^{-03}
Koc - Organic-carbon adsorption constant (ml g^{-1})	55,000

Table 2-2 lists the environmental fate properties of bromethalin, along with the major and minor degradates detected in the submitted environmental fate and transport studies.

Table 2-2. Summary of Bromethalin Environmental Fate Properties

Study	Value (units)	Major Degradates	MRID #	Study Status
Hydrolysis	Stable	None	42438701	Acceptable
Aerobic Soil Metabolism	178 days	desnitrobromethalin	43007901	Acceptable

The available data are sufficient for a cursory environmental fate assessment for the current use pattern. The data submitted indicate that bromethalin is stable to hydrolysis and is persistent (half-life = 178 days) to aerobic soil metabolism. The half-life of the parent is therefore 178 days.

i. Degradation

Hydrolysis: [^{14}C]bromethalin, at approximately 1 ppm, was stable in aqueous buffered pH 5, 7, and 9 solutions that were incubated at 25 ^{o}C in the dark for 30 days. At 35 days posttreatment, bromethalin comprised 91.2-99.9% of the radioactivity in the three buffer solutions and was the only [^{14}C]compound detected. At the conclusion of the study, the material balance for the three solutions was 93.0-100.0% of the applied radioactivity.

ii. Metabolism

Aerobic Soil Metabolism: Parent compound accounted for 102.4% of the applied radioactivity at the start and decreased to 22.3% by the end of the study. The calculated half-life for parent compound was 178 days ($y = -0.0039x + 4.38$, $r = -0.954$). The parent compound would be expected to be relatively stable to microbial/chemical degradation in the soil.

Up to 15.4% of the applied radioactivity was non-extractable residues; while up to 5.1% of the applied radioactivity was ^{14}C-volatiles, including 2.2% CO_2. Because the concentration of volatiles was so low, no attempt was made to characterize them. Unknown degradates ranged up to 3.6% of applied. One degradate at a concentration of 43.8% of the applied was identified as desnitrobromethalin.

iii. Mobility

Leaching/adsorption/desorption: The extremely low application rate and high Koc value (15,000) makes leaching unlikely.

iv. Degradates of Concern

The major degradate detected in the aerobic soil metabolism study, desnitrobromethalin, comprised up to 43% of the applied material in an aerobic soil metabolism study (MRID 43007901). This degradate appears to be persistent, but its mobility is unknown. Because leaching of bromethalin from bait products is expected to be minimal, formation of this degradate in soil and water is expected to be negligible. Furthermore, because the majority of risk to the assessed species is expected to result from direct consumption of bait products or from consumption of prey which directly consumed the bait, formation of this degrade in the soil and water is not a major concern in this assessment.

2.4.2. Environmental Transport Mechanisms

Potential transport mechanisms typically include pesticide surface water runoff, spray drift, and secondary drift of volatilized or soil-bound residues leading to deposition onto nearby or more distant ecosystems. However, because the only use of bromethalin is in bait for rodent and mole control, no potential for spray drift exists, and exposure from volatilization is expected to be minimal. Because bromethalin bait may be used outdoors, some potential exist for residues of bromethalin to leach from the bait that is exposed to rainwater or runoff. However, due to the extremely low concentration of active ingredient in the bait and the hydrophobic nature of the

compound, leaching would be so small that the potential for contaminating surface water is believed to be insignificant. Furthermore, because of placement of the active ingredient in highly hydrophobic, weather-resistant paraffinized blocks, volatilization from the bait is also expected to be insignificant. In the aerobic soil metabolism study, the concentration of volatiles was so low that no attempt was made to characterize them.

Another possible route of transport is within the bodies of animals which feed on the bromethalin bait. Because poisoned animals would not be killed immediately, they would travel some distance before dying, thereby potentially exposing animals some distance away from the use site. This transport within animals is an important route of exposure for the AW since its diet includes small mammals, and thus it is vulnerable to secondary exposure from consuming poisoned rodents.

2.4.3. Mechanism of Action

The mode of action of bromethalin is completely different than anticoagulant rodenticides commonly used in rodenticide bait products, such as brodifacoum and bromadialone. Bromethalin is a neurotoxicant that causes adverse effects and histological changes to the central nervous system. Van Lier and Cherry (1988) determined that acute toxicity is caused by the uncoupling of mitochondrial oxidative phosphorylation. This leads to fluid build-up and demethylination inside the central nervous system, eventually leading to respiratory failure because of lack of nerve impulse transmission to the lungs. While both bromethalin and the primary metabolite desmethylbromethalin are active in uncoupling oxidative phosphorylation, the desmethylbromalin metabolite is much more potent than the parent compound. Therefore, the rapid transformation of bromethalin into desmethylbromethalin in mammals (other than the guinea pig) is largely responsible for the high acute toxicity of this compound in most mammals (Van Lier and Cherry, 1988). A single feeding of bromethalin may be lethal with death being delayed for two or three days (Spaulding et al, 1985), although doses in excess of the LD50 may cause death within 8-12 hr (Van Lier and Cherry, 1988). Exposure to bromethalin at levels that do not cause acute respiratory failure causes intramyelenic edema and spongy degeneration of white matter of the brain, spinal cord, and optic nerve (Van Lier and Cherry, 1988; Dorman et al., 1992).

2.4.4. Use Characterization

Analysis of labeled use information is the critical first step in evaluating the federal action. The current labels for bromethalin represent the FIFRA regulatory action; therefore, labeled use and application rates specified on the label form the basis of this assessment. The assessment of use information is critical to the development of the action area and selection of appropriate modeling scenarios and inputs.

Nationwide, bromethalin is registered for use in baits for control of rodents and moles. It is registered for use to control three commensal rodents, the Norway rat (*Rattus norvegigus*), the roof rat (*Rattus rattus*), and the house mouse (*Mus musculus*), and certain moles, including the eastern moles (*Scalopus aquaticus*), the star-nose mole (*Conylura cristata*), and moles of in the genus *Scapanus*. The broad-footed mole, *Scapanus latimanus*, occurs in the region of central

California where the AW and SMHM occur. All three of the commensal rodent species also occur here. Therefore, all registered products of bromethalin could be used in the area inhabited by the assessed species. Rodent control baits containing bromethalin are registered for use in and around buildings, inside transport and cargo vehicles, in urban allies, and in sewers. Bromethalin products may be used in and around any type of building, including residential, commercial, industrial, and commercial structures, as well as transportation ports and terminals. For outdoor application, rodent control bait containing bromethalin must be placed within 50 feet of an exterior wall. Bromethalin bait used for controlling moles may be used on residential, commercial, or industrial lawns, around homes, in recreation areas, on golf courses, and in nurseries. Placement of bromethalin for controlling moles is not limited to areas adjacent to buildings.

Labels of bromethalin product do not limit the amount of product or active ingredient that may be applied per unit area, the number of applications that can be made per unit time, or the minimal time interval between applications. Labels generally state the number of bait stations, bait blocks, or bait packages that may be placed in one location, and the linear interval between placements. The linear interval is generally 15 to 30 feet for rats, 8 to 12 feet for mice, and 5 to 10 feet for moles. The concentration of bromethalin in the bait is set at 0.01% for all rodent-control products and at 0.025% in the single product for mole control (Talpirid®, EPA Registration Number 12455-101). The amount of active ingredient per placement, or the amount of active ingredient per linear foot, can be calculated for many, but not all, products. The maximum known amount of active ingredient per placement for any product is 5.00×10^{-5} lbs. The maximum known amount of active ingredient per linear foot is 6.25×10^{-6} lb/ft for controlling mice and 3.33×10^{-6} lb/ft for controlling rats. The maximum amount of bait per placement, and thus the maximum amount of active ingredient per placement, is not defined for use in sewage systems or for the product used to control moles (Talpirid®). Use information for applications considered in this assessment is summarized in Table 2-3**.**

Table 2-3. Bromethalin Uses Assessed for California

Use (App. Method)	Formulation	% AI in Bait	Maximum App. Rate per Bait Placement (lbs a.i./placement)	Bait Placement Interval
Bait for rat and mouse control in and around buildings and transportation vehicles	Pellets or blocks	0.01	0.00005	8-12 ft (mice) 15-30 ft (rats)
Rodent control bait for use in sewers	Pellets or blocks	0.01	NS	NS
Bait placed in mole runways to control moles	Impregnated material shaped to mimic worms or grubs	0.025	NS	NS

Abbreviations: App. = application, NS = not stated.

The Agency's Biological and Economic Analysis Division (BEAD) provides an analysis of both national- and county-level usage information (USEPA, 2011) using state-level usage data obtained Doane (www.doane.com) (the full dataset is not provided due to its proprietary nature) and the California's Department of Pesticide Regulation Pesticide Use Reporting (CDPR PUR) database[2]. CDPR PUR is considered a more comprehensive source of usage data the Doane database, and thus the usage data reported for bromethalin by county in this California-specific assessment were generated using CDPR PUR data. Eleven years (1999-2009) of usage data were included in this analysis. Data from CDPR PUR were obtained for every agricultural pesticide application made on every use site at the section level (approximately one square mile) of the public land survey system.[3] BEAD summarized these data to the county level by site, pesticide, and unit treated. Calculating county-level usage involved summarizing across all applications made within a section and then across all sections within a county for each use site and for each pesticide. The county level usage data that were calculated include: average annual pounds applied, average annual area treated, and average and maximum application rate across all eleven years. The units of area treated are also provided where available.

CDPR PUR data show that bromethalin is used in all of the counties in California where the AW and SMHM may occur (Table 2-4). For the AW, these counties are Alameda, San Joaquin, and Santa Clara. For the SMHM, these counties are Alameda, Contra Costa, Marin, Napa, Solano, and Sonoma. Due to its use as vertebrate control bait products, the pattern of use of bromethalin is characterized as numerous applications of small amounts of active ingredient. The average annual use per county was no more than 0.11 pounds for any county (Table 2-4). Unlike typical agricultural pesticides, the area treated was generally not reported in this database, and therefore the average application rate (lbs ai/A) could not be calculated. Use sites listed in the database for bromethalin use in counties where the assessed species occur include animal premise, landscape maintenance, public health, recreation area, right-of-way, structural pest control, and vertebrate control. As noted above, this database does not include residential use of bromethalin. However, for reasons listed above, the total amount of active ingredient applied is expected to be very small.

Table 2-4. Summary of California Department of Pesticide Registration (CDPR) Pesticide Use Reporting (PUR) Data from 1999 to 2007 for Currently Registered Bromethalin Uses[1]

County	Average Annual Pounds Applied	Number of Record
Alameda	0.017	653
Contra Costa	0.034	896
Marin	0.006	294
Napa	0.005	256
San Joaquin	0.107	275
Santa Clara	0.086	936

[2] The California Department of Pesticide Regulation's Pesticide Use Reporting database provides a census of pesticide applications in the state. See http://www.cdpr.ca.gov/docs/pur/purmain.htm.

[3] Most pesticide applications to parks, golf courses, cemeteries, rangeland, pastures, and along roadside and railroad rights of way, and postharvest treatments of agricultural commodities are reported in the database. The primary exceptions to the reporting requirement are home-and-garden use and most industrial and institutional uses (http://www.cdpr.ca.gov/docs/pur/purmain.htm).

County	Average Annual Pounds Applied	Number of Record
Solano	0.004	201
Sonoma	0.015	307

1 Based on data supplied by BEAD (USEPA, 2011).

2.5. Assessed Species

Table 2-5 provides a summary of the current distribution, habitat requirements, and life history parameters for the listed species being assessed. More detailed life-history and distribution information can be found in Attachment III. See Figure 2-1 for a map of the current range and designated critical habitat of the AW, and Figure 2-2 for a map of the current range of the SMHM.

The AW, a subspecies of the California whipsnake (*Masticophis lateralis*), was listed as threatened in 1997 by the USFWS. A recovery plan for this and other threatened and endangered species of the chaparral and scrub community east of San Francisco Bay, California was approved by the USFWS in 2003. Critical habitat was designated for this subspecies in 2006. The subspecies occurs in the Inner Coast Ranges in Contra Costa, Alameda, San Joaquin, and possibly Santa Clara Counties (see **Figure 2-1**).

The SMHM was listed as an endangered species by the USFWS in 1970. A recovery plan for the SMHM was approved by the USFWS in 1973. No critical habitat has been designated for this species. The species is found in tidal and non-tidal salt marshes around the margins and tributaries of the San Francisco, San Pablo, and Suisun Bays (see Figure 2-2).

Table 2-5. Summary of Current Distribution, Habitat Requirements, and Life History Information for the Assessed Listed Species[1]

Assessed Species	Size	Current Range	Habitat Type	Designated Critical Habitat?	Reproductive Cycle	Diet
Alameda Whipsnake (AW) (*Masticophis lateralis euryxanthus*)	3 – 5 ft	Contra Costa and Alameda Counties in California (additional occurrences in San Joaquin and Santa Clara Counties)	Primarily, scrub and chaparral communities. Also found in grassland, oak savanna, oak-bay woodland, and riparian areas. Lands containing rock outcrops, talus, and small mammal burrows.	Yes	Emerge from hibernation and begin mating from late March through mid-June. Females lay eggs in May through July. Eggs hatch from August through November. Hibernate during the winter months.	Lizards, small mammals, nesting birds, other snakes including rattlesnakes
Salt Marsh Harvest Mouse (SMHM) (*Reithrodontomys raviventris*)	Adult 8 – 14 g	Northern subspecies can be found in Marin, Sonoma, Napa, Solano, and northern Contra Costa counties. The southern subspecies occurs in San Mateo, Alameda, and Santa Clara counties with some isolation populations in Marin and Contra Costa counties.	Dense, perennial cover with preference for habitat in the middle and upper parts of the marsh dominated by pickleweed and peripheral halophytes as well as similar vegetation in diked wetlands adjacent to the Bay	No	Breeding: March – November Gestation period: 21 – 24 days	Leaves, seeds, and plant stems; may eat insects; prefers "fresh green grasses" in the winter and pickleweed and saltgrass during the rest of the year; drinks both salt and fresh water

[1] For more detailed information on the distribution, habitat requirements, and life history information of the assessed listed species, see Attachment II.

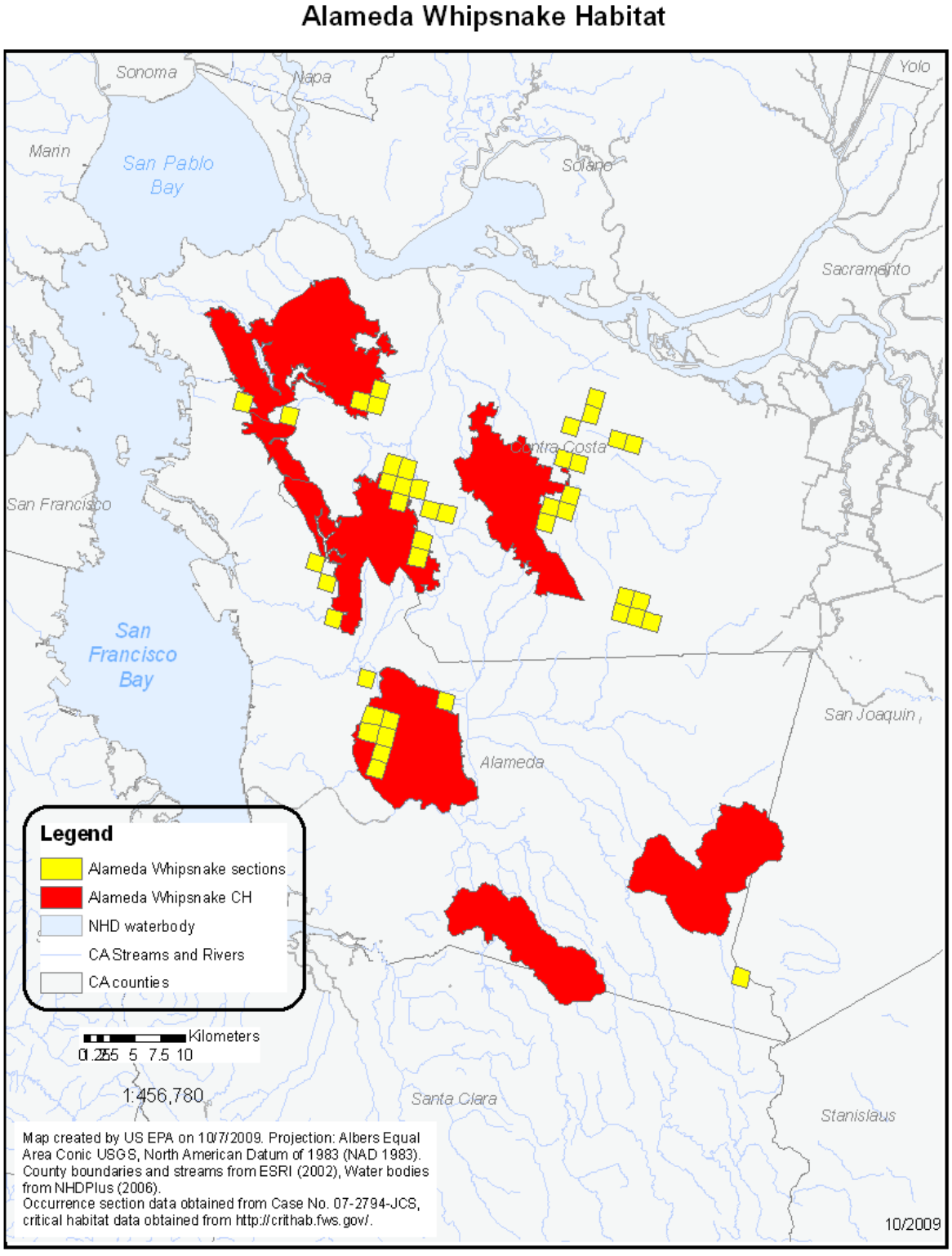


Figure 2-1. Critical habitat and occurrence sections of the Alameda whipsnake, as identified in Case No. 07-2794-JCS.

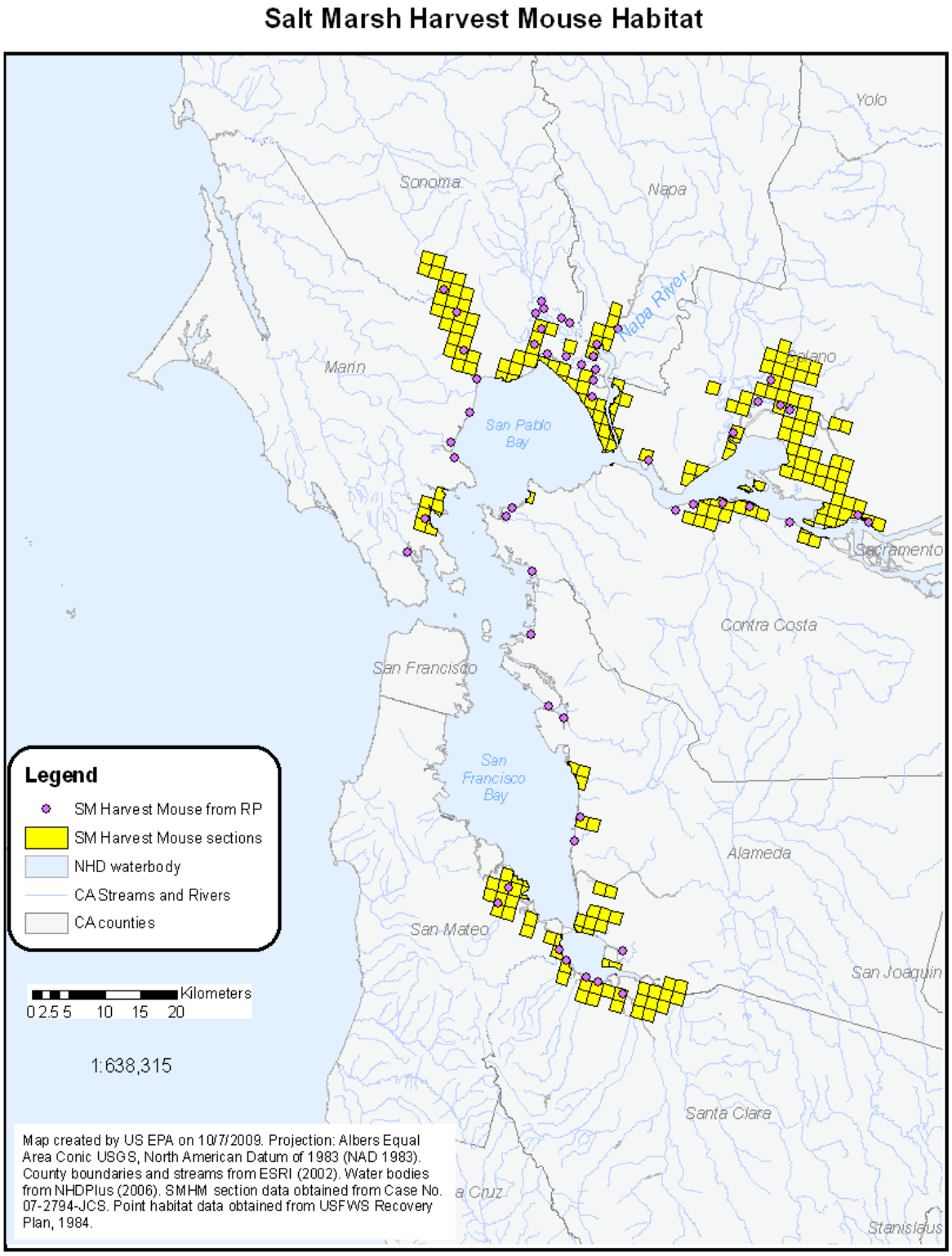


Figure 2-2. Occurrences and occurrence sections of the salt marsh harvest mouse, as identified in Case No. 07-2794-JCS.

2.6. Designated Critical Habitat

Critical habitat has been designated for the AW. Six segments of critical habitat have been designated for this species in Contra Costa, Alameda, San Joaquin, and Santa Clara Counties (see Figure 2-1). Risk to critical habitat is evaluated separately from risk to effects on the species. 'Critical habitat' is defined in the ESA as the geographic area occupied by the species at the time of the listing where the physical and biological features necessary for the conservation of the species exist, and there is a need for special management to protect the listed species. It may also include areas outside the occupied area at the time of listing if such areas are 'essential to the conservation of the species. Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species or areas that contain certain primary constituent elements (PCEs) (as defined in 50 CFR 414.12(b)). Table 2-6 describes the PCEs for the critical habitats designated for the AW.

Table 2-6. Designated Critical Habitat PCEs for the Alameda Whipsnake[1].

PCE #	PCEs	Reference
1	Scrub/shrub communities with a mosaic of open and closed canopy	71 FR 58175 58231, 2006
2	Woodland or annual grassland plant communities contiguous to lands containing PCE 1	
3	Lands containing rock outcrops, talus, and small mammal burrows within or adjacent to PCE 1 and or PCE 2	

[1] These PCEs are in addition to more general requirements for habitat areas that provide essential life cycle needs of the species such as, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing (or development) of offspring; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species.

Activities that may destroy or adversely modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the species. As previously noted in Section 2.1, the Agency believes that the analysis of direct and indirect effects to listed species provides the basis for an analysis of potential effects on the designated critical habitat. Because bromethalin is expected to directly impact living organisms within the action area, critical habitat analysis for bromethalin is limited to those PCEs of critical habitat that are biological or that can be reasonably linked to biologically mediated processes. More detail on the designated critical habitat applicable to this assessment can be found in Attachment II.

2.7. Action Area and LAA Effects Determination Area

2.7.1. Action Area

The action area is used to identify areas that could be affected by the Federal action. The Federal action is the authorization or registration of pesticide use or uses as described on the label(s) of pesticide products containing a particular active ingredient. The action area is defined by the Endangered Species Act as, "all areas to be affected directly or indirectly by the Federal action

and not merely the immediate area involved in the action" (50 CFR §402.2). Based on an analysis of the Federal action, the action area is defined by the actual and potential use of the pesticide and areas where that use could result in effects. Specific measures of ecological effect for the assessed species that define the action area include any direct and indirect toxic effect to the assessed species and any potential modification of its critical habitat, including reduction in survival, growth, and fecundity as well as the full suite of sublethal effects available in the effects literature. It is recognized that the overall action area for the national registration of bromethalin is likely to encompass considerable portions of the United States based on its widespread use for rodent control. However, the scope of this assessment limits consideration of the action area to the state of California. For this assessment, the entire state of California is considered the action area. The purpose of defining the action area as the entire state of California is to ensure that the initial area of consideration encompasses all areas where the pesticide may be used now and in the future. Additionally, the concept of a state-wide action area takes into account the potential for direct and indirect effects and any potential modification to critical habitat based on ecological effect measures associated with reduction in survival, growth, and reproduction, as well as the full suite of sublethal effects available in the effects literature. It is important to note that the state-wide action area does not imply that direct and/or indirect effects and/or critical habitat modification are expected to occur over the full extent of the action area, but rather to identify all areas that may potentially be affected by the action.

2.7.2. LAA Effects Determination Area

Typically, when assessing the potential for use of a pesticide to affect threatened or endangered species, the Agency determines a Likely to Adversely Affect (LAA) Effects Determination Area. This is the area where the pesticide's use is expected to directly or indirectly affect the species and/or modify its designated critical habitat, as determined by applying EFED's standard assessment procedures (see Attachment I) based on effects endpoints related to survival, growth, and reproduction. The LAA Effects Determination Area is typically designated as the area where the land use corresponds with land use on which the pesticide is likely to be used (e.g. row crops or orchards), plus the area outside this use area which could receive exposure via spray drift and/or downstream transport at levels that are potentially toxic for the species of concern. In the case of this assessment, however, the area of potential use of bromethalin is not restricted spatially. Considering the use pattern of rodent and mole control baits, bromethalin potentially could be used in any terrestrial land use type. Thus, any area of the state of California is considered an area of potential use of bromethalin bait, and thus the assessed species potentially could be exposed to bromethalin wherever they occur.

2.8. Assessment Endpoints and Measures of Ecological Effect

2.8.1. Assessment Endpoints

A complete discussion of all the toxicity data available for this risk assessment, including resulting measures of ecological effect selected for each taxonomic group of concern, is included in Section 4 of this document. Table 2-7 identifies the taxa used to assess the potential for direct and indirect effects from the uses of bromethalin for each listed species assessed here. For the AW, birds are used to assess direct effects because they are used as a surrogate for assessing risk

to reptiles when reptilian toxicity data are not available. Birds, mammals, and terrestrial invertebrates are assessed for indirect effects as these taxa are prey of the AW. Small mammals are also important habitat component of the AW because this snake uses small mammal burrows for shelter and for sites to lay eggs (NatureServe, 2010). In addition, terrestrial plants are assessed as an important habitat component of the AW. For the SWHM, mammals are assessed for direct effects. Terrestrial plants, aquatic plants (in particular emergent aquatic plants), and terrestrial invertebrates are assessed for indirect effects because they provide food for the SMHM. Terrestrial plants and emergent aquatic plants also play a role as important habitat requirements of the SMHM. In addition to plants, birds and mammals are assessed as habitat requirements because this species is known to build its nests over bird nests (USF&WS, 2007) and in abandoned nests built by shrews (Goals Project, 2007).

Table 2-7. Taxa Used in the Analyses of Direct and Indirect Effects for the Assessed Listed Species.

Listed Species	Birds	Mammals	Terr. Inverts.	Terr. Plants	Aquatic Plants
Alameda whipsnake	Direct[1] and Indirect (prey)	Indirect (prey and habitat)	Indirect (prey)	Indirect (habitat)	n/a
Salt marsh harvest mouse	Indirect (rearing sites)	Direct and Indirect (rearing sites)	Indirect (prey)	Indirect (food and habitat)	Indirect (food and habitat)

Abbreviations: n/a = Not applicable; Terr. = Terrestrial; Invert. = Invertebrate; FW = Freshwater
[1] Birds are used as surrogates for assessing direct effects to reptiles.

Assessment endpoints used to assess the direct and indirect effects are acute and chronic endpoints obtained from toxicological studies of appropriate animal and plant taxa. These specific assessment endpoints are provided in Table 2-8. For more information on the assessment endpoints, measures of ecological effect, see Attachment I.

Table 2-8. Taxa and Assessment Endpoints Used to Evaluate the Potential for Use of Bromethalin to Result in Direct and Indirect Effects to the Assessed Listed Species or Modification of Critical Habitat

Taxa	Assessed Listed Species	Assessment Endpoints	Measures of Ecological Effects
Birds	Direct Effect -Alameda Whipsnake	Survival, growth, and reproduction of individuals via direct effects	Acute: Most sensitive bird[1] acute LC_{50} or LD_{50} Chronic: Most sensitive bird[1] chronic NOAEC
	Indirect Effect -Salt Marsh Harvest Mouse (rearing sites) -Alameda Whipsnake (prey)	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects	
Mammals	Direct Effect -Salt Marsh Harvest Mouse	Survival, growth, and reproduction of individuals via direct effects	Acute: Most sensitive laboratory mammalian acute LC_{50} or LD_{50} Chronic: Most sensitive laboratory mammalian chronic NOAEC
	Indirect Effect -Salt Marsh Harvest Mouse (rearing sites) - Alameda Whipsnake (prey)	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on terrestrial prey (mammals) and/or	

Taxa	Assessed Listed Species	Assessment Endpoints	Measures of Ecological Effects
		burrows/rearing sites	
Terrestrial Invertebrates	Indirect Effect (prey) -Salt Marsh Harvest Mouse (prey) -Alameda Whipsnake (prey)	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on terrestrial prey	Acute: Most sensitive terrestrial invertebrate acute EC_{50} or LC_{50} Chronic: Most sensitive terrestrial invertebrate chronic NOAEC
Terrestrial Plants	Indirect Effect -Salt Marsh Harvest Mouse (food/habitat) -Alameda Whipsnake (habitat)	Survival, growth, and reproduction of individuals or modification of critical habitat/habitat via indirect effects on food and habitat	Distribution of EC_{25} values for seedling emergence and vegetative vigor of monocots and dicots
Aquatic Plants (freshwater and saltwater)	Indirect Effect -Salt Marsh Harvest Mouse (food and habitat)	Survival, growth, and reproduction of individuals via indirect effects on habitat, cover, food supply, and/or primary productivity	Most sensitive EC_{50} for growth and reproduction of vascular and nonvascular plants.

Abbreviations: SF=San Francisco
[1] Birds are used as a surrogate for terrestrial-phase amphibians and reptiles.

2.8.2. Assessment Endpoints for Designated Critical Habitat

As previously discussed, designated critical habitat is assessed to evaluate actions related to the use of bromethalin that may alter the PCEs of the designated critical habitat of the AW. PCEs for this species were previously described in Section 2.6. Actions that may modify critical habitat are those that alter the PCEs and jeopardize the continued existence of the assessed species. Therefore, these actions are identified as assessment endpoints. It should be noted that evaluation of PCEs as assessment endpoints is limited to those of a biological nature (*i.e.*, the biological resource requirements for the listed species associated with the critical habitat) and those for which bromethalin effects data are available.

Assessment endpoints used to evaluate potential effects to designated critical habitat are equivalent to the assessment endpoints used to evaluate potential for direct and indirect effects. For the AW, relevant the assessment endpoints for critical habitat are those that measure effects of bromethalin on the survival and reproduction of terrestrial plants and small mammals. Effects on small mammals are important because the presence of small mammal burrows is a component of PCE 3 of the AW. If a potential for direct or indirect effects to terrestrial plants and small mammals is found, then there is also a potential for effects to critical habitat. Some components of these PCEs are associated with physical abiotic features (*e.g.*, presence of rock outcroppings), which are not expected to be measurably altered by use of pesticides.

2.9. Conceptual Model

2.9.1. Risk Hypotheses

Risk hypotheses are specific assumptions about potential adverse effects (*i.e.*, changes in assessment endpoints) and may be based on theory and logic, empirical data, mathematical

models, or probability models (USEPA, 1998a). For this assessment, the risk is stressor-linked, where the stressor is the release of bromethalin to the environment. The following risk hypotheses are presumed in this assessment:

The labeled use of bromethalin within the action area may:

- directly affect the AW and SMHM by causing mortality or by adversely affecting growth or fecundity;
- indirectly affect the AW and SMHM and/or modify the designated critical habitat of the AW by reducing or changing the composition of food supply;
- indirectly affect the SMHM by reducing or changing the composition of the aquatic plant community in the species' current range, thus affecting primary productivity and/or cover;
- indirectly affect the AW and SMHM and/or modify their designated critical habitat of the AW by reducing or changing the composition of the terrestrial plant community in the species' current range;
- indirectly affect the AW and SMHM and/or modify their designated critical habitat of the AW by reducing or changing terrestrial habitat in their current range (via reduction in availability of small burrowing mammals burrows used by the AW for cover, or bird and /or small mammal nests used by the SMHM for nest sites).

2.9.2. Diagram

The conceptual model is a graphic representation of the structure of the risk assessment. It specifies the bromethalin release mechanisms, biological receptor types, and effects endpoints of potential concern. The conceptual model for the possible effects of bromethalin on the AW and SMHM is shown in Figure 2-3. Typically a separate diagram is created for terrestrial and aquatic exposure and effects. For this assessment, however, only a single diagram of terrestrial exposure and effects is depicted because use of bromethalin bait is not expected to result in any significant exposure or effects to the assessed species through aquatic pathways. Although the conceptual models for direct/indirect effects and modification of designated critical habitat PCEs are shown on the same diagram, the potential for direct/indirect effects and modification of PCEs will be evaluated separately in this assessment. Exposure routes shown in dashed lines are not quantitatively considered because the contribution of those potential exposure routes to potential risks to the AW and SMHM, and modification to designated critical habitat of the AW, is expected to be negligible.

As shown in the diagram, we consider exposure through consumption of intact bait to be the primary route of exposure to the SMHM and the AW. This includes direct consumption of intact bait (primary exposure) and consumption of terrestrial vertebrates which consumed intact bait (secondary exposure). The quantitative risk assessment therefore focused on these routes of exposure. Exposure and indirect effects to these species mediated through plants and terrestrial invertebrates are possible but are believed to have negligible contribution to overall risk to these species. These presumed negligible exposure routes and indirect effects include:

- Consumption of terrestrial invertebrates which consume intact bait.

- Consumption of terrestrial invertebrates which ingested soil contaminated by dislodgement of bromethalin from the intact bait.
- Consumption of plants which have taken up bromethalin from residues dislodged from the bait into the soil.
- Indirect food chain effects resulting from bromethalin reducing the abundance of plants and terrestrial invertebrates.

A diagram of exposure routes through water and aquatic organisms was not created because all such exposure routes were considered negligible for the SMHM and AW (Section 2.10.1.a).

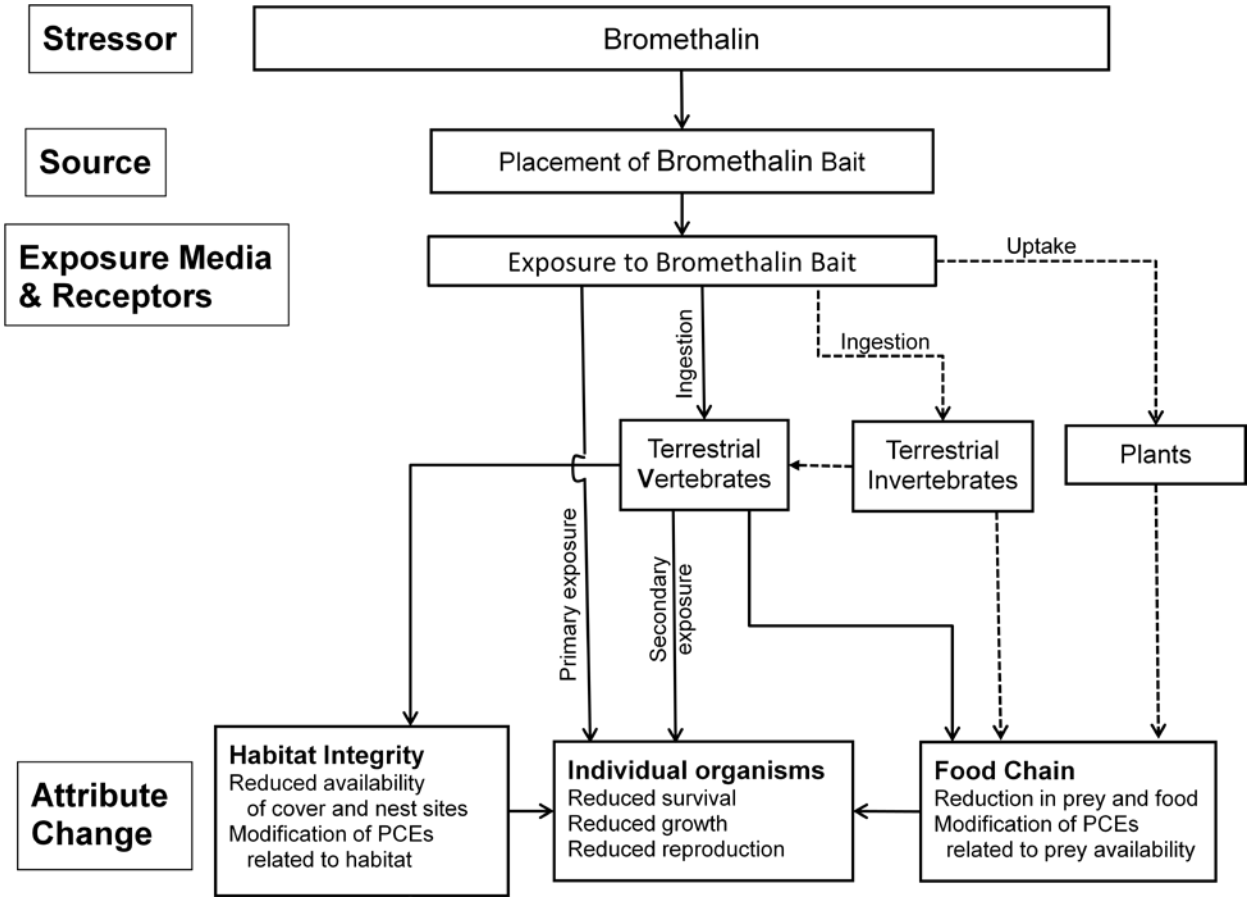


Figure 2-3. Conceptual model depicting stressors, exposure pathways, and potential effects to terrestrial organisms from the use of bromethalin.
Dotted lines indicate exposure pathways that have a low likelihood of contributing to ecological risk.

2.10. Analysis Plan

In order to address the risk hypotheses, the potential for direct and indirect effects to the assessed species, prey items, and habitat was estimated based on a taxon-level approach. In the following

sections, the use, environmental fate, and ecological effects of bromethalin are characterized and integrated to assess the risks. This integration was accomplished using a risk quotient (ratio of exposure concentration to effects concentration) approach. Although risk is often defined as the likelihood and magnitude of adverse ecological effects, the risk quotient-based approach does not provide a quantitative estimate of likelihood and/or magnitude of an adverse effect. However, as outlined in the Overview Document (USEPA, 2004), the likelihood of effects to individual organisms from particular uses of bromethalin is estimated using the probit dose-response slope and either the level of concern (discussed below) or actual calculated risk quotient value. Descriptions of routine procedures for evaluating risk to the San Francisco Bay Species are provided in Attachment I.

As explained in the previous section, risk to the SMHM and AW from use of bromethalin bait is expected to result primarily from consumption of terrestrial vertebrates to intact bait. This ingestion of intact bait may result in direct consumption of the bait by the assessed species (i.e., primary exposure), or ingestion of intact bait by terrestrial vertebrates which are important to the assessed species as prey (in the case of the AW) or as a principal habitat component (in the case of both the SMHM and the AW). Therefore, the quantitative risk assessment will include an assessment of risk to terrestrial vertebrates from direct consumption of bait (primary exposure), as well as an assessment of risk resulting from consumption of other terrestrial organisms which directly ingested the intact bait (secondary exposure). Exposure routes mediated through exposure to terrestrial plants and terrestrial invertebrates were considered negligible and were not evaluated with a quantitative risk assessment. Finally, for the reasons listed in the previous section, risk to the assessed species resulting from contamination of water and harm to aquatic organisms was considered to be negligible for these assessed species. Therefore, no aquatic risk assessment was conducted.

2.10.1. Measures of Exposure

The primary pathways of exposure of terrestrial animals to bromethalin are through direct ingestion of bromethalin bait, or consumption of another animal that directly ingested the bait. Because bromethalin is only used in bait for vertebrate pest control, and outdoor uses are limited to around buildings, in sewers, or in mole runways, exposure to plants is expected to be minimal. Therefore, exposure to bromethalin from consumption of plants is expected to be minimal.

2.10.1.a. Estimating Exposure in the Aquatic Environment

Because bromethalin is used only in bait that is placed by hand, there is no potential for the product to be transported by drift. Furthermore, much bromethalin bait used for rodent control is placed indoors or outdoors within plastic bait stations. These uses would pose minimal potential for transport to surface water or ground water. For other outdoor use, bromethalin is used only in bait products with extremely small quantities of active ingredient, and thus contact of this chemical with surface water is expected to be negligible. The extremely low application rate and high K_{oc} value (15,000) also makes leaching unlikely. Even for use in sewers, where some potential contact with water is possible, little bromethalin is expected to be released from the bait into water because the water solubility of bromethalin is very low (2 µg/L), and bait products

used in sewers are formulated in highly hydrophobic, weather-resistant paraffinized blocks. Furthermore, the maximum application rate of active ingredient in sewers is extremely small (0.0000375 pounds AI per placement).

The only aquatic species that would be relevant to this assessment are aquatic plants for indirect effects to the SMHM. Concentrations of bromethalin in saltwater marshes are also expected to be negligible and not impact aquatic vegetation. Therefore, models that estimate concentrations in surface water or calculate spray drift deposition of bromethalin on aquatic habitats were not needed for this assessment. No surface water monitoring data are available for bromethalin.

2.10.1.b. Estimating Exposure in the Terrestrial Environment

The SMHM is likely to consume bromethalin bait if it encounters it. Therefore, the terrestrial exposure for this species was based on dietary exposure to the bait itself. The concentration of bromethalin in the diet of this species was assumed to be equal to the maximum concentration of bait in products registered for rodent control and mole control uses. Indirect risk to both the SMHM and the AW were also assessed by assessing risk to mammals, birds, reptiles, and terrestrial-phase amphibians that may directly consume the bait. Dietary exposure to these species thus also was assumed to be equal to the bromethalin concentrations in the bait products. For the AW, the primary route of exposure was assumed to be from secondary poisoning, that is from consumption of prey which fed directly on bromethalin bait. The prey species was assumed to be one of the target species, the Norway rat, the house mouse, or the broad-footed mole. The residues of bromethalin in the prey were assumed to be the amount that the prey would consume in one day if it fed on the bait. All of the residues consumed by the prey were assumed to be available and assimilated by the snake when it consumed the prey.

2.10.2. Measures of Effect

Data identified in Section 2.8 are used as measures of effect for direct and indirect effects. Data were obtained from registrant submitted studies or from literature studies identified by ECOTOX. More information on the ECOTOXicology (ECOTOX) database and how toxicological data is used in assessments is available in Attachment I.

2.10.3. Integration of Exposure and Effects

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from uses of bromethalin, and the likelihood of direct and indirect effects to the assessed species. Because the use of bromethalin in bait products is not expected to result in any significant exposure to aquatic organisms (Section 2.10.1.a), risk from bromethalin was characterized only for terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. The risk quotient (RQ) method is used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's levels of concern (LOCs) (USEPA, 2004, Appendix **C**B). More information on standard assessment procedures is available in Attachment I.

2.10.4. Data Gaps

None of the data requirements identified in the 1998 RED for data related to characterizing the ecological fate and effects of bromethalin remain outstanding. However, data are lacking to fully characterize the risk bromethalin products pose to wildlife from secondary exposure. The accumulation and persistence of bromethalin residues in the tissue of animals which feed on bromethalin bait is poorly understood. Also, while the risk of secondary poisoning was identified by the risk assessment, this risk is uncertain because it is not confirmed by documented incidents of secondary poisoning caused by this pesticide. Data from studies on the secondary poisoning potential of bromethalin in a bird and a mammal species would serve to reduce the uncertainty regarding secondary poisoning. One secondary poisoning study with dogs is available (Van Lier, 1981), but this study was not adequately described, tested dogs rather than a prey species, and used bait with a bromethalin concentration less than the highest concentration of registered products. Additional studies would expose animals to rodents which were killed by feeding on bromethalin bait and then aged for various durations. Data from such studies would characterize how tissue levels of bromethalin would remain at levels hazardous to predators or scavengers that feed on the carcasses.

3. Exposure Assessment

Bromethalin is formulated as solid bait products. The bait can be in the form of pellets, paraffinized blocks, or for mole control, bait shaped to mimic worms and grubs. Baits are placed by hand; they may not be broadcasted. Since there is no potential for spray drift, no spray drift analysis was conducted for this assessment.

3.1. Label Application Rates and Intervals

Bromethalin labels may be categorized into two types: labels for manufacturing uses (including technical grade bromethalin) and end-use products. While technical products, which contain bromethalin of high purity, are not used directly in the environment, they are used to make formulated products, which can be applied in specific areas to control vertebrate pests. The formulated product labels legally limit bromethalin's potential use to only those sites that are specified on the labels.

Labels of bromethalin product do not limit the amount of product or active ingredient that may be applied per unit area, the number of applications that can be made per unit time, or the minimal time interval between applications. Labels generally state the number of bait stations, bait blocks, or bait packages that may be placed in one location, and the linear interval between placements. The linear interval is generally 15 to 30 feet for rats, 8 to 12 feet for mice, and 5 to 10 feet for moles. The concentration of bromethalin in the bait is set at 0.01% for all rodent-control products and at 0.025% in the single product for mole control (Talpirid®, EPA Registration Number 12455-101). The amount of active ingredient per placement, or the amount of active ingredient per linear foot, can be calculated for many, but not all, products. The maximum known amount of active ingredient per placement for any product is 5.00×10^{-5} lbs. The maximum known amount of active ingredient per linear foot is 6.25×10^{-6} lb/ft for

controlling mice and 3.33 x 10^{-6} lb/ft for controlling rats. The maximum amount of bait per placement, and thus the maximum amount of active ingredient per placement, is not defined for use in sewage systems or for the product used to control moles (Talpirid®). Use information for applications considered in this assessment is summarized in Table 3-1.

Table 3-1. Bromethalin Uses and Application Information.

Use (App. Method)	Formulation	% AI in Bait	Maximum App. Rate per Bait Placement (lbs a.i./placement)	Bait Placement Interval and Restrictions
Bait for rat and mouse control in and around buildings and transportation vehicles	Pellets or blocks	0.01	0.00005	8-12 ft (mice) 15-30 ft (rats) Bait must be placed within 50 ft of a building
Rodent control bait for use in sewers	Pellets or blocks	0.01	NS	NS
Bait placed in mole runways to control moles	Impregnated material shaped to mimic worms or grubs	0.025	NS	NS

Abbreviations: App. = application, NS = not stated.

3.2. Aquatic Exposure Assessment

3.2.1. Modeling Approach

Aquatic exposure from use of bromethalin was assumed to be negligible (see Section 2.10.1.a.). Therefore, no aquatic exposure assessment was carried out.

3.2.2. Existing Monitoring Data

No monitoring data in surface water, in groundwater or in air were found from the USGS NAWQA program (http://water.usgs.gov/nawqa), the California Department of Pesticide Regulation CDPR (http://www.cdpr.ca.gov/docs/emon/surfwtr/surfcont.htm) or from the USEPA STORET program. Water monitoring programs such as these generally monitor for agricultural pesticides and typically do not include analysis for vertebrate control agents such as bromethalin.

3.3. Terrestrial Animal Exposure Assessment

3.3.1. Exposure to Terrestrial Wildlife from Primary Exposure

For assessing exposure of pesticides to terrestrial animals, the Agency typically uses T-REX to calculate EECs for dietary exposure of terrestrial wildlife, and T-HERPS to calculate refined EECs for dietary exposure to reptiles and amphibians. However, these models only calculate EECs (and risk quotient based on the EECs) for natural wildlife food items such as plants, seeds, and insects that are exposed from foliar application of pesticides. These models are not

appropriate for calculating EECs for animals that directly consume bait products, or that consume other animals which consume the bait products. These models also calculate risk quotients (RQs) for application of granular pesticides and seed treatment uses, but cannot be used to calculate RQs for bait products. Therefore, terrestrial animal exposure to bromethalin was calculated without use of computer models.

For animals that directly consume bromethalin bait (i.e., primary exposure), the EEC is simply the concentration of bromethalin in the formulated bait itself. Assessments were based on the maximum concentration of bromethalin in bait products used for rodent control and for mole control. The maximum concentration is 0.01% (100 ppm) for products used to control rats and mice, and 0.025 % (250 ppm) for the product used to control moles (Table 3-2). For dietary-based risk assessments, the concentration of bromethalin in the bait was compared directly to the toxicity endpoint from dietary toxicity studies (the 8-day LC_{50} and the NOAEC from chronic toxicity studies expressed as a dietary dose). For dosed-based risk assessments, the bromethalin concentrations in bait had to first be converted to a daily ingestion rate. This was done using the allometric equations of Nagy (1987), as provided in USEPA's Wildlife Exposure Factor Handbook (USEPA, 1993). Ingested doses of bromethalin (mg ai/kg-BW) were calculated for birds and mammals of various assumed body weights. The doses calculated for birds were used in preliminary risk assessments for reptile and terrestrial-phase amphibians, as well as for birds. A refined exposure assessment for primary exposure to the AW was not conducted because snakes seldom consume anything except live prey and therefore the AW would not likely consume bromethalin bait directly.

Table 3-2. Use Information Used to Establish Terrestrial EECs for Bromethalin

	Formulation	**% AI in Bait**	**Dietary EEC for Primary Exposure (mg ai/kg-diet)**
Bait for rat and mouse control in and around buildings	Pellets or blocks	0.01	100
Bait placed in mole runways to control moles	Impregnated material shaped to mimic worms or grubs	0.025	250

3.3.2. Exposure to Terrestrial Animals from Secondary Exposure

Secondary exposure was also assessed for assessing risk to the AW. This species may be exposed if it consumes a vertebrate animal that has eaten bromethalin bait. Lizards in particular are believed to be the most important prey item of whipsnakes (USFWS, 2005), but lizards generally feed upon insects and other terrestrial arthropods and would not likely consume rodent bait. Therefore, secondary exposure was based on consumption of small mammals, which are also a component of the diet of the AW. Secondary exposure is not likely for the SMHM because it eats mainly plant material. For assessing secondary exposure for the AW, scenarios were considered in which a snake preyed upon a house mouse, a broad-footed mole, or a Norway rat after they prey had consumed bromethalin bait. The prey animal was assumed to have consumed a quantity of bait equal to its daily ingestion rate. In one set of scenarios, the entire quantity of active ingredient ingested was assumed to remain in the animal at the time it was consumed. This could occur if the animal was consumed immediately after it ate the bait as the

entire amount ingested would be present in the gastrointestinal tract of the prey animal. This scenario represents the high-end of possible secondary exposure. A second set of exposure scenarios was also used to represent more typical conditions. In these scenarios, the prey animal was assumed to have been eaten 24 hours after it had consumed bromethalin bait.

The maximum size of the prey consumed by snakes may be estimated using the following allometric equation developed by King (2002).

$$\text{Prey Size (g)} = \text{Snake body weight (g)}^{1.071}$$

To make this assessment protective, the exponent used in this equation is the upper limit of the 95% confidence interval that King (2002) reported for this parameter. (This is the same relationship that is assumed in the T-HERPS model.) The weight of the AW was not available, but the Agency has estimated body weight of this species from its length using the method presented in USEPA (1993). The body weights of this species were estimated to range from 2.5 to 176 g for juveniles, and 46 to 897 g for adults (USEPA 2010). Using the upper bounds of these ranges, and the allometric equation given above, the maximum prey size for the AW was estimated to be 254 g for juvenile snakes and 1450 g for adult snakes. Reported body weights of house mice, eastern mole, and Norway rat are 18-23 g, 82-140 g, and 195-485 g, respectively (Whitaker, 1996). (The body weight of the broad-footed mole was not reported, but reported lengths indicate its size is similar to the eastern mole.) Therefore, the AW is predicted to be able to consume all three of these prey species, including the Norway rat. In this assessment, the upper limit of the reported ranges was used for the body weight of each prey (23 g for the house mouse, 140 g for the broad-footed mole, and 485 g for the Norway rat.)

To make the risk assessment protective, the size of the AW was set at the minimum size animal that could consume prey of the size assumed for the three prey species. This was done by setting the prey size in the allometric equation for maximum prey size, given above, and solving for snake body weight. The minimum snake size to consume the mouse, mole, and rat was calculated to be 18.6, 101, and 322 g, respectively. The 18.6-g snake is plausible for a juvenile AW, the 322-g snake is plausible for an adult AW, and the 101-g snake is plausible for either an adult or large juvenile AW.

3.3.3. Exposure to Terrestrial Invertebrates

As described in Section 2.9, indirect effects to the SMHM and AW mediated through exposure to terrestrial invertebrates are expected to be negligible. It is possible that some terrestrial invertebrates could directly consume bromethalin bait and that the bromethalin exposure could cause some mortality of such invertebrates. However, given the outdoor use of bromethalin bait is restricted to areas adjacent to walls of buildings and to inside mole runways, any mortality of invertebrates would be very localized. The impact to the invertebrate abundance throughout the range of the assessed species is expected to be negligible. Therefore, no exposure assessment was conducted for terrestrial invertebrates.

3.4. Terrestrial Plant Exposure Assessment

Because of the use pattern of bromethalin, exposure to terrestrial plants was assumed to be negligible. Therefore, no terrestrial plant exposure assessment was conducted.

4. Effects Assessment

This assessment evaluates the potential for bromethalin to directly or indirectly affect the AW and SMHM or modify their designated critical habitat. Assessment endpoints for the effects determination for each assessed species include direct toxic effects on the survival, reproduction, and growth, as well as indirect effects, such as reduction of the prey base or modification of its habitat. In addition, potential modification of critical habitat is assessed by evaluating effects to the PCEs, which are components of the critical habitat areas that provide essential life cycle needs of each assessed species. Direct effects to reptiles such as the AW are based on avian toxicity data, given that birds are generally used as a surrogate for terrestrial-phase amphibians and reptiles.

As described in the Agency's Overview Document (USEPA, 2004), the most sensitive endpoint for each taxon is used for risk estimation. For this assessment, evaluated taxa include birds (which are used as a surrogate for terrestrial-phase amphibians and reptiles), mammals, terrestrial arthropods, and terrestrial plants, and aquatic plants. Acute (short-term) and chronic (long-term) toxicity information is characterized based on registrant-submitted studies and a comprehensive review of the open literature on bromethalin.

4.1. Ecotoxicity Study Data Sources

Toxicity endpoints are established based on data generated from guideline studies submitted by the registrant, and from open literature studies that meet the criteria for inclusion into the ECOTOX database maintained by EPA/Office of Research and Development (ORD) (USEPA, 2004). Open literature data presented in this assessment were obtained from ECOTOX literature searches conducted in January 2005 and October 2010, as well as papers cited in the 2004 rodenticide comparative assessment (USEPA, 2004). In order to be included in the ECOTOX database, papers must meet the following minimum criteria:

(1) the toxic effects are related to single chemical exposure;
(2) the toxic effects are on an aquatic or terrestrial plant or animal species;
(3) there is a biological effect on live, whole organisms;
(4) a concurrent environmental chemical concentration/dose or application rate is reported; and
(5) there is an explicit duration of exposure.

Open literature toxicity data on the effects of bromethalin to 'target' rodent species (the house mouse, the Norway rat, and the wood rat), which include efficacy studies, were not considered in deriving the most sensitive endpoint for terrestrial mammals. In the case of rodenticides, adequate data on the toxicity to rats and mice are already provided by acute mammalian toxicity

studies that the rodenticide registrants are required to submit for product registration. Therefore, toxicological data on target species of rats and mice were not included in the ECOTOX open literature search that the Agency conducted, and are not included in the summary table provided in Appendix D. Citations of open literature papers that provide toxicological data for target rodent species are listed in Appendix C with the code "TARGET" given after the citation. While toxicological findings were not included in the summary of acute and chronic toxicity endpoints in this document, some of these papers which were deemed useful were obtained and used to provide supplemental information for characterizing the toxicity of bromethalin, such as information on the sublethal effects and the mode of action of bromethalin.

Data that pass the ECOTOX screen are evaluated along with the registrant-submitted data, and may be incorporated qualitatively or quantitatively into this endangered species assessment. In general, effects data in the open literature that are more conservative than the registrant-submitted data are considered. The degree to which open literature data are quantitatively or qualitatively characterized for the effects determination is dependent on whether the information is relevant to the assessment endpoints (*i.e.*, survival, reproduction, and growth) identified in Section 2.8. For example, endpoints such as behavior modifications are likely to be qualitatively evaluated, because quantitative relationships between modifications and reduction in species survival, reproduction, and/or growth are not available. Although the effects determination relies on endpoints that are relevant to the assessment endpoints of survival, growth, or reproduction, it is important to note that the full suite of sublethal endpoints potentially available in the effects literature (regardless of their significance to the assessment endpoints) are considered, as they are relevant to the understanding of the area with potential effects, as defined for the action area.

Citations of all open literature not considered as part of this assessment because they were either rejected by the ECOTOX screen or accepted by ECOTOX but not used (*e.g.*, the endpoint is less sensitive) are included in Appendix C. Appendix C also includes a rationale for rejection of those studies that did not pass the ECOTOX screen and those that were not evaluated as part of this endangered species risk assessment. A detailed spreadsheet of the available ECOTOX open literature data, including the full suite of lethal and sublethal endpoints is presented in Appendix D. Appendix E includes a summary of the human health effects data for bromethalin.

In addition to registrant-submitted and open literature toxicity information, other sources of information, including use of the acute probit dose response relationship to establish the probability of an individual effect and reviews of ecological incident data, are considered to further refine the characterization of potential ecological effects associated with exposure to bromethalin. A summary of the available aquatic and terrestrial ecotoxicity information and the incident information for bromethalin are provided in Sections 4.2 and 4.3.

4.2. Toxicity of Bromethalin to Aquatic Organisms

Toxicity data on effects of bromethalin to fish and aquatic organisms are not relevant to the risk assessment of the AW or SMWM. The only aquatic taxa that is relevant for this assessment is aquatic plants, which is an important component of the habitat of the SMHM. However, due to the use pattern of bromethalin, exposure to aquatic plants in salt marsh habitat of the SMHM is expected to be negligible.

4.3. Toxicity of Bromethalin to Terrestrial Organisms

Table 4-1 summarizes the most sensitive terrestrial toxicity endpoints, based on an evaluation of both the submitted studies and the open literature. A summary of submitted and open literature data considered relevant to this ecological risk assessment is presented below.

Table 4-1. Terrestrial Toxicity Profile for Bromethalin

Endpoint	Acute/ Chronic	Species	Toxicity Value Used in Risk Assessment	Citation MRID/ ECOTOX reference No.	Comment
Birds (surrogate for terrestrial-phase amphibians and reptiles)	Acute Oral	Northern bobwhite (*Colinus virginianus*)	14-day LD_{50} = 4.56 mg/kg bw	MRID 00086742 (van Lier et al. 1981)	This study was classified as *Acceptable*.
	Subacute Dietary	Northern bobwhite (*Colinus virginianus*)	8-day LC_{50} = 210 mg ai/kg-diet	MRID 00086745 Kehr et al. 1981	This study was classified as *Acceptable*.
	Chronic	--	--	--	No avian reproduction data has been submitted.
Mammals	Acute	Norway Rat (*Rattus norvegicus*)	14-day LD50 = 2.11 mg/kg-bw	MRID 44775101	This study was classified as *Acceptable*.
	Chronic	Rabbit	NOAEC = 3.3 mg ai/kg-diet LOAEC = 8.25 mg ai/kg-diet (decreased weight gain and clinical signs of toxicity.)	MRID 00101545	This study was classified as *Acceptable*.

n/a: not applicable; ND = not determined; bw = body weight

Data are not available to characterize the toxicity of bromethalin to nontarget invertebrates (e.g. honey bees) or to terrestrial or aquatic plants.

Acute toxicity to terrestrial animals is categorized using the classification system shown in Table 4-2 (USEPA, 2004). Toxicity categories for terrestrial plants have not been defined.
Toxicity data categorizes bromethalin as *very highly toxic* to birds and mammals on an acute oral basis, and *highly toxic* to birds on a subacute dietary basis.

Table 4-2. Categories of Acute Toxicity for Avian and Mammalian Studies

Toxicity Category	Oral LD_{50}	Dietary LC_{50}
Very highly toxic	< 10 mg/kg	< 50 mg/kg-diet
Highly toxic	10 - 50 mg/kg	50 - 500 mg/kg-diet
Moderately toxic	51 - 500 mg/kg	501 - 1000 mg/kg-diet
Slightly toxic	501 - 2000 mg/kg	1001 - 5000 mg/kg-diet
Practically non-toxic	> 2000 mg/kg	> 5000 mg/kg-diet

4.3.1. Toxicity to Birds, Reptiles, and Terrestrial-Phase Amphibians

As specified in the Overview Document, the Agency uses birds as a surrogate for reptiles and terrestrial-phase amphibians when toxicity data for each specific taxon are not available (USEPA, 2004). A summary of acute and chronic bird data, including data published in the open literature, is provided below.

Table 4-3 summarizes findings of studies on acute to birds when bromethalin is administered as a single oral dose. These data classify bromethalin as *very highly toxic* to birds when the ingredient is ingested in a polyethylene glycol vehicle and as *highly toxic* to birds when the ingredient is ingested in an acacia vehicle. Table 4-4 summarizes findings of studies on subacute toxicity to birds when bromethalin is administered in the diet. The results for the northern bobwhite categorize bromethalin as *very highly toxic* to birds when administered through the diet. Additional data on the acute toxicity of bromethalin to birds have been reported in the open literature (e.g. Spaulding et al. 1985, van Lier and Cherry, 1985), but they were not used in this assessment because study methodology were not reported and therefore the studies could not be evaluated for acceptability.

Table 4-3. Acute Oral Toxicity of Bromethalin to Birds

Species, Test substance	% AI	LD_{50} (mg/kg-bw) (95% confidence interval)	MRID or ECOTOX	Classification
Northern bobwhite (*Colinus virginianus*), bromethalin with acacia vehicle	96.3	14-day LD_{50} = 11.0 (9.3-13.1)	MRID 00086741 Ecoref No. 150772 (van Lier et al. 1981)	Acceptable
Northern bobwhite (*Colinus virginianus*), bromethalin with polyethylene glycol vehicle	96.3	14-day LD_{50} = 4.56* (3.6-5.8) Slope[1]: 3.64	MRID 00086742 (van Lier et al. 1981)	Acceptable
Northern bobwhite (*Colinus virginianus*), bromethalin with acacia vehicle	96.3	14-day LD_{50} < 160 (100% mortality on Day 2)	Ecoref No. 150787 (van Lier et al. 1980)	Qualitative[2]

*Endpoint used for quantitative assessment of risks.
[1] The slope was calculated by the author of this document.
[2] This study was submitted to the Office of Pollution Prevention and Toxics, but has not been submitted to or reviewed by the Office of Pesticide Programs.

Table 4-4. Subacute Dietary Toxicity of Bromethalin to Birds

Species	% AI	LC_{50} (mg/kg-diet) (95% confidence interval)	MRID or ECOTOX	Classification
Northern bobwhite (*Colinus virginianus*)	96.3	8-day LC_{50} = 21* (15-28)	MRID 00086744 (van Lier et al. 1981)	Acceptable
Northern bobwhite (*Colinus virginianus*)	96.3	8-day LC_{50} > 50 (20% mortality at 50 ppm)	MRID 00086745 Ecoref No. 150767	Qualitative[1]
Northern bobwhite (*Colinus virginianus*)	96.3	5-day LC_{50} > 200 (40% mortality at 200 ppm)	Ecoref No. 150784	Qualitative[1]
Mallard duck (*Anas platyrhynchos*)	96.3	8-day LC_{50} = 62 (46-82)	MRID 00086746 (van Lier et al. 1981)	Acceptable

*Endpoint used for quantitative assessment of risks.
[1] This study was submitted to the Office of Pollution Prevention and Toxics, but has not been submitted to or reviewed by the Office of Pesticide Programs.

In these studies, bromethalin was observed to cause sublethal effects in birds at oral doses as low as 2.75 mg/kg-bw and at dietary doses as low as 12.5 mg/kg-diet. Observed sublethal effects are summarized in Table 4-5. The only sublethal effect that was associated with mortality was convulsions, and that occurred at levels greater than the median lethal dose. Thus, none of these sublethal effects represent a more sensitive acute endpoint than LD_{50} and LC_{50} endpoints used in this risk assessment. Acute oral studies conduct using polyethylene glycol as a vehicle consistently shows greater toxicity than those conducted using acacia. As a result, the NOAEL and LOAEL for sublethal effects were lower in the acute oral study conducted with polyethylene glycol (MRID 00086742) than in the one conducted with acacia (MRID 00086741).

Table 4-5. Sublethal Effects of Bromethalin Observed in Acute Avian Toxicity Studies

Symptom	NOAEL	LOAEL	Reference
Acute Oral Studies			
Lethargy	Not determined	2.75 (mg/kg-bw)	00086742
	3.65 (mg/kg-bw)	5.00 (mg/kg-bw)	00086741
Ataxia	Not determined	2.75 (mg/kg-bw)	00086742
	3.65 (mg/kg-bw)	5.00 (mg/kg-bw)	00086741
Loose feces/diarrhea	Not determined	2.75 (mg/kg-bw)	00086742
	5.00 (mg/kg-bw)	7.00 (mg/kg-bw)	00086741
Reduced food consumption	Not determined	2.75 (mg/kg-bw)	00086742
Clonic convulsions followed by death	3.65 (mg/kg-bw)	5.00 (mg/kg-bw)	0008742
Reduced bodyweight gain	5.00 (mg/kg-bw)	7.00 (mg/kg-bw)	0008741
Dietary Studies			
Lethargy	6.25	12.5	Ecoref No. 150767, MRID 86745
	25	50	Ecoref No. 150784, MRID 86746
Ataxia	6.25	12.5	Ecoref No. 150767,

			MRID 86745
	25	50	Ecoref No. 150784, MRID 86746
Tremors	25	50	Ecoref No. 150784
	50	100	MRID 86746
Convulsions	50	100	MRID 86746
Reduced bodyweight gain	25	50	Ecoref No. 150767, MRID 86745
	50	100	MRID 86746
Reduced food consumption	50	100	MRID 86746

No data are available on the effects of chronic exposure of birds to bromethalin.

4.3.2. Toxicity to Mammals

A summary of acute and chronic mammalian data, including data published in the open literature, is provided below. A more complete analysis of toxicity data to mammals is available in Appendix E, which is a copy of the Health Effects Division (HED) chapter prepared in support of the reregistration eligibility decision completed in 1998.

4.3.2.a. Mammals: Acute Exposure (Mortality) Studies

Table 4-6 summarizes findings of studies on the acute of bromethalin to mammals. These data classify bromethalin as *very highly toxic* to mammals. The lowest acute oral toxicity LD_{50} from a fully acceptable (MRID 44775101) study was 2.57 mg ai/kg-BW. This value, which was based on the combined results for males and females, was used in the quantitative acute risk assessment for mammals. Risk based on the LD_{50} value for females was also considered in the risk characterization for the SMHM. The slightly lower LD_{50} value obtained for the Norway rat with bromethalin administered in PEG-200 (2.0 mg ai/kg-BW, MRID 00026523) was not used because the Health Effects Division assigned an acceptability category of "minimum" to this study, indicating that the study was only marginally acceptable, and because the percent active ingredient of the test material was not reported.

Table 4-6. Summary of Findings of Acute Toxicity of Bromethalin to Mammals

Species	Test Material (Reg. Number)	% AI	14- d LD_{50} (mg ai/kg-bw)[1]	MRID, Citation	Classification
Norway Rat (*Rattus norvegicus*)	TGAI	98.3	Female: 2.11 (1.71-2.55) Male: 3.17 (2.54-5.41) Combined[2]: 2.57* (2.19-3.04) Slope: 6.51	44775101	Acceptable
Norway Rat (*Rattus norvegicus*)	TGAI in Acacia	0.005%	Female: 9.1 ± 1.2 Male: 10.7 ± 1.3	00026523	Minimum
Norway Rat (*Rattus norvegicus*)	TGAI in PEG-200		Female: 2.0 ± 0.2 Male: 2.4 ± 0.1	00026523	Minimum

Species	Test Material (Reg. Number)	% AI	14- d LD_{50} (mg ai/kg-bw)[1]	MRID, Citation	Classification
House mouse (*Mus musculus*)	TGAI in PEG-200		Female: 8.1 ± 0.6 Male: 5.3 ± 0.6	00026523	Minimum
House mouse (*Mus musculus*)	TGAI in Acacia		Female: 28.9 ± 5.0 Male: 35.9 ± 3.4	00026523	Minimum
Domestic cat (*Felis domesticus*)	TGAI in PEG-200		1.8 ± 0.9	00026523	Minimum
Domestic dog (*Canis familiaris*)	TGAI in PEG-200		4.5	00026523	Minimum

*Endpoint used for quantitative assessment of risks.
[1] 95% confidence intervals are given in parentheses when available.
[2] Results for combined sexes were calculated by the author.

Additional toxicity information on the acute toxicity of bromethalin to nontarget species are available from the comparative study of Hanasono et al. (1979). These results are summarized in Table 4-7. These same study results are also provided in published papers, including Spaulding et al. (1985) and Van Lier and Cherry (1988).

Table 4-7. Results of a Comparative Toxicity Study on the Lethality of Bromethalin to Various Mammals (MRID 26523, Hanasono et al. 1979)

Species	Vehicle	LD_{50} ± S.E. (mg ai/kg-bw)	Signs of Toxicity
Mouse (*Mus musculus*)	Acacia	*Females*: 28.9 ± 5.0 *Males*: 35.9 ± 3.4	Hyperactivity, loss of righting reflex, tremors, dyspnea, ptosis, diarrhea, and diuresis.
	PEG-200	*Females*: 8.1 ± 0.6 *Males*: 5.3 ± 0.6	
Rat (*Rattus norvegicus*)	Acacia	*Females*: 9 ± 1.2 *Males*: 10.7 ± 1.3	Hyperactivity, loss of righting reflex, tremors, dyspnea, ptosis, diarrhea, and diuresis.
	PEG-200	*Females*: 2.0 ± 0.2 *Males*: 2.4 ± 0.1	
New Zealand albino rabbit	PEG-200	12.6 ± 2.3	Labored breathing, tonic convulsions
Cat	PEG-200	1.8 ± 0.9	Hind limb weakness at 1.0 and 5.0 mg/kg
Dog	PEG-200	4.8 ± 3.3	Anorexia, emesis, weakness and stiffness in hind limbs, hyperthermia, and fine tremors.

Khan and Rizvi (2000) conducted a no-choice efficacy test with the lesser bandicoot rat which provides additional information on the acute toxicity of bromethalin to mammals. Adult rats were deprived of food for three hours, and then allowed to feed on corn flour containing bromethalin at concentrations between 10 and 100 mg/kg diet. Five males and five females were tested at each concentration. The bandicoot rats were fed treated feed for 4 days, and then

observed for 14 days. Results of this test are given in Table 4-8. When the dose is expressed as a dietary concentration, this test yielded an 18-day LC_{50} of 18.4 mg/kg-diet (95% CI 9.09 – 29.1). When the dose was converted to a dose of active ingredient ingested, the test yielded an LD_{50} of 2.51 mg/kg-bw (95% CI 1.54-3.26). These results are very similar to those obtained in the single-dose acute oral test with the Norway rat (MRID 44775101, Table 4-6).

Table 4-8. Summary of a One-Choice Efficacy Study with the Lesser Bandicoot Rat (*Bandicota bengalensis*) (from Khan and Rizvi, 2000)

Concentration (ppm)	Mean Body Weight (g)	Mean Food Ingested (g)	Bromethalin Ingested (mg/kg-bw)	Mortality
10	217.41	37.62	1.72	3/10 (33%)
20	228.77	32.59	2.84	5/10 (50%)
50	230.78	22.99	5.00	8/10 (80%)
100	228.31	12.42	5.01	10/10 (100%)

In mammalian studies, bromethalin was observed to cause sublethal effects at oral doses as low as 1.0 mg/kg-bw and at dietary doses as low as 8.25 mg/kg-diet. Observed sublethal effects are summarized in Table 4-9. Open literature publications on the toxicity of bromethalin report similar sublethal effects, including lethargy, hind leg weakness, loss of muscle tone, loss of tactile sensation, and paralysis (Spaulding et al., 1985, Van Lier and Cherry, 1988, Dorman et al., 1992). These sublethal observations were similar to those observed in birds and were consistent with the neurotoxic mode of action of bromethalin. In addition to these behavioral effects, exposure to bromethalin has been found to cause histological changes, including formation of vacuoles, in tissues of the central nervous system. These histological changes are associated with intramyelenic endema and spongy degeneration of white matter of the brain, spinal cord, and optic nerve (Van Lier and Cherry, 1988; Dorman et al., 1992).

The only sublethal effects that may be associated with mortality were convulsions and labored respiration. These effects occurred at levels greater than the median lethal dose. Therefore, none of these sublethal effects represent a more sensitive acute endpoint than LD_{50} endpoint used in this risk assessment.

Table 4-9. Sublethal Effects of Bromethalin Observed in Mammalian Toxicity Studies

Symptom	Species	NOAEL	LOAEL	Reference
Acute Oral Studies				
Hind leg weakness/paralysis	Rat	< 2.5 mg/kg-bw	2.5 mg/kg-bw	MRID 0002625
	Bandicoot rat	NS	NS	Khan and Rizvi (2000)
	Dog	NS	NS	MRID 00026523
	Cat	0.5 mg/kg-bw	1.0 mg/kg	MRID 00026523
Hypoactivity	Rat	< 2.5 mg/kg-bw	2.5 mg/kg-bw	MRID 0002625
	Rat	NS	NS	MRID 00026523
	Mouse	NS	NS	MRID 00026523
Dyspnea	Rat	< 2.5 mg/kg-bw	2.5 mg/kg-bw	MRID 0002625
	Rat	NS	NS	MRID 00026523

	Mouse	NS	NS	MRID 00026523
Loss of righting reflex/prostration	Rat	2.5 mg/kg-bw	4.5 mg/kg-bw	MRID 0002625
	Rat	NS	NS	MRID 00026523
	Mouse	NS	NS	MRID 00026523
	Rabbit	4 mg/kg-bw	10 mg/kg-bw	MRID 0002623
	Dog	NS	NS	MRID 00026523
	Bandicoot rat	NS	ND	Khan and Rizvi (2000)
Tremors	Rat	7.5 mg/kg-bw	12.5 mg/kg-bw	MRID 00026525
	Rat	NS	NS	MRID 00026523
	Mouse	NS	NS	MRID 00026523
	Dog	NS	NS	MRID 00026523
Ataxia	Dog	NS	NS	MRID 00026523
Anorexia	Bandicoot rat	NS	NS	Khan and Rizvi (2000)
	Dog	NS	NS	MRID 00026523
Emesis	Dog	NS	NS	MRID 00026523
Hyperthermia	Dog	NS	NS	MRID 00026523
Convulsions followed by death	Rat	7.5 mg/kg-bw	12.5 mg/kg-bw	MRID 00026525
	Rabbit	10 mg/kg-bw	20 mg/kg-bw	MRID 00026523
	Bandicoot rat	NS	NS	Khan and Rizvi (2000)
Labored respiration	Rabbit	10 mg/kg-bw	10 mg/kg-bw	MRID 00026523
Chronic Dietary Studies				
Hind leg weakness/paralysis	Rat	6 mg/kg-diet	10 mg/kg-diet	MRID 00086731
Decreased muscle tone	Rat	6 mg/kg-diet	10 mg/kg-diet	MRID 00086731
	Rabbit	3.3 mg/kg-diet	8.25 mg/kg-diet	MRID 00101545
Weakness	Rat	6 mg/kg-diet	10 mg/kg-diet	MRID 00086731
	Rabbit	3.3 mg/kg-diet	8.25 mg/kg-diet	MRID 00101545
Decreased/labored respiration	Rat	6 mg/kg-diet	10 mg/kg-diet	MRID 00086731
	Rabbit	3.3 mg/kg-diet	8.25 mg/kg-diet	MRID 00101545
Prostration	Rat	6 mg/kg-diet	10 mg/kg-diet	MRID 00086731
	Rabbit	3.3 mg/kg-diet	8.25 mg/kg-diet	MRID 00101545
Hypothermia	Rat	6 mg/kg-diet	10 mg/kg-diet	MRID 00086731
Dehydration	Rat	6 mg/kg-diet	10 mg/kg-diet	MRID 00086731
Nasal discharge	Rabbit	3.3 mg/kg-diet	8.25 mg/kg-diet	MRID 00101545
Coolness	Rabbit	3.3 mg/kg-diet	8.25 mg/kg-diet	MRID 00101545
Decrease Weight Gain	Rat	6 mg/kg-diet	10 mg/kg-diet	MRID 00086731
	Rabbit	3.3 mg/kg-diet	8.25 mg/kg-diet	MRID 00101545
Decreased food consumption	Rat	6 mg/kg-diet	10 mg/kg-diet	MRID 00086731

4.3.2.b. Mammals: Chronic Exposure Studies

Two developmental studies provide chronic toxicity endpoints which are related to survival, growth, or reproduction. Results from these studies are summarized in Table 4-10. No toxic effects were in the offspring in either of these developmental studies, but maternal toxic effects were observed in the dosed adult females in both studies. The lowest NOAEL established by these studies, 3.3 mg/kg-diet for maternal toxicity in the rabbit, was used as the chronic mammalian endpoint for quantitative risk assessment.

Table 4-10. Chronic Mammalian Toxicity Data for Bromethalin

Species	% AI	NOAEC (mg/kg-diet)	LOAEC (mg/kg-diet) Effected Parameters	Reference	Classification
Rat	96.3	6	10 *Maternal toxicity:* 4 deaths, 30.2% decreased weight gain, upper respiratory infection believed resulting from physiological stress	MRID 00086731	Acceptable
Rabbit	96.3	3.3 *	8.25 *Maternal toxicity at 8.25 mg/kg-diet:* decreased weight gain and clinical signs of toxicity. *Maternal toxicity at 16.5 mg/kg-diet:* 2 deaths, decrease in weight gain, 1 case of pneumonia and 1case of upper respiratory infection	MRID 00101545	Acceptable

*Endpoint used for quantitative assessment of risks.

4.3.2.c. Mammals: Secondary Hazard and Metabolism Studies

Secondary hazard is the hazard posed to a predator or scavenger that feeds on an animal that directly feeds on the toxicant. In the case of bromethalin, small mammals that feed on the bromethalin bait may pose a secondary hazard to any predator or scavenger which may feed on small mammals, including the AW. Only one study is available that attempted to measure this secondary hazard directly. Van Lier (1981) observed domestic dogs which were offered 600 g of ground meat obtained from rats which fed on bait containing 0.005% bromethalin for one day. Four dogs were exposed to the meat for 14 days. During the study, no dogs died, and no signs of toxicity were observed, indicating that 0.005% bromethalin bait does not pose a secondary hazard to dogs. It should be noted, however, that bromethalin bait is registered at concentrations up to 0.01% for rodent control and 0.025% for mole control. Thus, this study does not preclude secondary hazard to predators and scavengers from registered bromethalin products.

Data on the metabolism of bromethalin in rats also provide insight in the secondary hazard of bromethalin by providing information on how long toxic residues will remain in the tissue of small mammals killed by bromethalin bait. A metabolism study was conducted with Fischer 344 rats that evaluated disappearance of radiolabeled bromethalin residues in the blood and tissue (liver and brain) following a single dose at 1 mg/kg. The terminal elimination half-life of

radiolabeled material was 134.8 ± 55.2 hr or approximately 5.6 days. The metabolite desmethylbromethalin was found to account for virtually all of the circulating radioactive material during the first 100 hr. The half-life of the distributive phase suggests distribution in total body water. The half-life for plasma clearance was found to be 3.6 hr. Desmethylbromethalin was found to be the primary metabolite in extracted tissue. (MRID 00146583, van Lier and Cherry, 1998)

The findings of this metabolism study indicate that bromethalin is transformed into the more active metabolite desmethylbromethalin, and that the residues of bromethalin and desmethylbromethalin are moderately persistent in body of the rat (half-life 5.6 days). This suggests that a potential exists for secondary poisoning if a predator preys upon a small mammal within a few days after it feeds on bromethalin bait.

4.3.3. Toxicity to Terrestrial Invertebrates

No data are available on the toxicity of bromethalin to terrestrial invertebrates. The mode of action of this pesticide (neurotoxicity related to uncoupling of oxidative phosphorylation) is relevant to invertebrates as well as vertebrates. Without data, the Agency therefore assumes that bromethalin is likely highly toxic to terrestrial invertebrates, as it is with vertebrates.

4.3.4. Toxicity to Terrestrial Plants

No data are available on the toxicity of bromethalin to terrestrial plants.

4.4. Toxicity of Chemical Mixtures

All registered products containing bromethalin contain only bromethalin as the single active ingredient. Therefore, no data has been submitted to the Agency on the toxicity of bromethalin and other pesticide active ingredients. A review of the open literature also found no published data of the toxicity of mixtures of bromethalin with other chemicals.

4.5. Incident Database Review

A review of the Ecological Incident Information System (EIIS, version 2.1), the 'Aggregate Incident Reports' (v. 1.0) database, and the Avian Monitoring Information System (AIMS) for ecological incidents involving bromethalin was completed on 29 December 2010. Only two incidents associated with bromethalin use have been recorded in these databases. Both of the incidents were in the EIIS database, and both were incidents of wildlife poisoning.

In 1996, AgrEvo USA Company reported to the EPA that use of their product Gold Crest Vengeance ® resulted in the poisoning of a chipmunk (I007155-060). The chipmunk was incapacitated after it consumed bait that had been placed to control mice or rats. The chipmunk was taken to a veterinary clinic for treatment. It is not known if the chipmunk survived. This product is no longer registered for use in the United States. However, this product was a rodenticide bait which contained 0.01% bromethalin, making it similar to other bromethalin rodenticide baits that are currently registered. This incident exemplifies that, as with any rodenticide bait, bromethalin bait can be hazardous to nontarget rodents when used outdoors.

The only other incident in which bromethalin was implicated at a possible cause was a case involving the death or incapacitation of several raptors which were held in captivity on Amicalola Falls State Park, Georgia, as part of an educational program (I014717-001). One red-tailed hawk and one barn owl were found incapacitated in their mews and later died. Two great-horned owls later were found exhibiting lethargy similar that observed in the birds that died. They were treated with vitamin K (an antidote to anticoagulant poisoning) and recovered. A half-eaten dead rat was found in the mew of the hawk, and a second dead rat was found between the hawk's mew and the owl's mew. Products which were reportedly in use in the park to control rodents were Maki Rat and Mouse Bait (EPA Reg No. 7173-188, active ingredient bromadialone), Contract Blox (EPA Reg No. 12455-104, active ingredient bromadialone), and Real Kill Rat and Mouse Killer (active ingredient bromethalin). While no use of a product containing brodifacoum was reported, analysis of a liver samples from the raptors found brodifacoum at 77 mg/kg-bw in the owl and at 7 mg/kg-bw in the hawk.

Evidence in this incident strongly indicates that the birds were poisoned by one or more anticoagulant rodenticides. Because brodifacoum and bromadialone are anticoagulant rodenticides whereas bromethalin does not cause anticoagulation, evidence indicate that the birds were poisoned by brodifacoum and/or bromadialone, not bromethalin. Because of this, a certainty index of "unlikely" was assigned to bromethalin in this incident.

The lack of wildlife incidents for bromethalin contrasts sharply with the large number of incidents that have been reported for rodenticides used to control rats and mice. A 2004 comparative assessment on the risk of various rodenticides to birds and nontarget mammals (USEPA, 2004) reported that there has been more than 300 mortality incidents in which one or more rodenticide was detected in birds or mammals, including more than 244 with detections of brodifacoum, 30 with detection of bromadiolone, 25 with detections of zinc phosphide, 20 with detection of diaphacinone, and 13 with detection of chlorophacinone. The lack of numerous wildlife incidents for bromethalin, despite its widespread use, suggests that it may pose less of a risk of primary and secondary poisoning to nontarget wildlife than other commonly used rodenticides. However, only a small fraction of wildlife incidents are believed to be reported to the Agency, and many factors other than lack of risk may contribute to number of reported incidents being low for a particular chemical. For one thing, it is not known if pesticide residue screens conducted in incident investigations routinely include bromethalin and its activated metabolite, desmethylbromethalin. Therefore, the lack of numerous reported incidents bromethalin cannot be used as evidence for lack of risk to listed wildlife species.

A field study conducted on the efficacy of bromethalin bait to control rodents is also consistent with this conclusion (Spaulding et al., 1985). In this study, the efficacy of 0.005% bromethalin bait to control the Norway rat and house mouse was evaluated in indoor and outdoor field trials in five geographical locations. Searches for carcasses of target and nontarget wildlife were made throughout the trials. The searches found numerous carcasses of the target species, ranging from 1 to 87 in the trials, but did not find any carcass of nontarget species. The published report on these field trials lacked details on the methodology used, such as where the bait was placed and how the carcass searches were conducted. Therefore, the quality of this study could not be evaluated by the Agency. In addition, the concentration of bromethalin in the bait used in these trials (0.005%) is less than what is in many registered bromethalin products. Bromethalin bait

registered for rodent control may contain up to twice the concentration of active ingredient (0.01%), and the bait registered for use to control moles contains five times the concentration of active ingredient (0.025%). Therefore, although these findings are consistent with a conclusion of low relative risk of primary and secondary exposure, they cannot be used as evidence that use of bromethalin bait poses insignificant risk of poisoning to listed wildlife species.

4.6. Use of Probit Slope Response Relationship to Provide Information on the Endangered Species Levels of Concern

The Agency uses the probit dose response relationship as a tool for providing additional information on the potential for acute direct effects to individual listed species and aquatic animals that may indirectly affect the listed species of concern (USEPA, 2004). As part of the risk characterization, an interpretation of acute RQs for listed species is discussed. This interpretation is presented in terms of the chance of an individual event (*i.e.*, mortality or immobilization) should exposure at the EEC actually occur for a species with sensitivity to bromethalin on par with the acute toxicity endpoint selected for RQ calculation. To accomplish this interpretation, the Agency uses the slope of the dose response relationship available from the toxicity study used to establish the acute toxicity measures of effect for each taxonomic group that is relevant to this assessment. The individual effects probability associated with the acute RQ is based on the mean estimate of the slope and an assumption of a probit dose response relationship. In addition to a single effects probability estimate based on the mean, upper and lower estimates of the effects probability are also provided to account for variance in the slope, if available.

Individual effect probabilities were calculated based on an Excel spreadsheet tool IECV1.1 (Individual Effect Chance Model Version 1.1) developed by the U.S. EPA, OPP, Environmental Fate and Effects Division (June 22, 2004). The model allows for such calculations by entering the mean slope estimate (and the 95% confidence bounds of that estimate) as the slope parameter for the spreadsheet. In addition, the acute RQ is entered as the desired threshold.

5. Risk Characterization

Risk characterization is the integration of the exposure and effects characterizations. Risk characterization is used to determine the potential for direct and/or indirect effects to the AW and SMHM, or for modification to the designated critical habitat of the AW, from the use of bromethalin in CA. The risk characterization provides an estimation (Section 5.1) and a description (Section 5.2) of the likelihood of adverse effects; articulates risk assessment assumptions, limitations, and uncertainties; and synthesizes an overall conclusion regarding the likelihood of adverse effects to the assessed species or their designated critical habitat (*i.e.*, "no effect," "likely to adversely affect," or "may affect, but not likely to adversely affect"). In the risk estimation section, risk quotients are calculated using standard EFED procedures and models. In the risk description section, additional analyses may be conducted to help characterize the potential for risk.

5.1. Risk Estimation

Risk is estimated by calculating the ratio of exposure to toxicity. This ratio is the risk quotient (RQ), which is then compared to pre-established acute and chronic levels of concern (LOCs) for each category evaluated (Appendix B). For acute exposures to the aquatic animals, as well as terrestrial invertebrates, the LOC is 0.05. For acute exposures to the birds (surrogates for reptiles and terrestrial-phase amphibians) and mammals, the LOC is 0.1. The LOC for chronic exposures to animals, as well as acute exposures to plants is 1.0.

5.1.1. Exposures in the Aquatic Habitat

Due to use pattern of this rodenticide in the environment, no significant aquatic exposure was expected. Therefore, no aquatic exposure assessment was done.

5.1.2. Primary Exposures in the Terrestrial Habitat

5.1.2.a. AW and Birds (Surrogate for Reptiles and Terrestrial-phase Amphibian)

As previously discussed in Section 3.3, potential direct effects to terrestrial species are based on placement of rodenticide bait containing bromethalin around buildings and in sewers, and in mole runways. Potential risks to birds, reptiles, and terrestrial-phase amphibians were evaluated for both primary and secondary exposure. Primary exposure was based on the animal directly consuming the bromethalin bait. This assessment was used to assess risk of direct effects to the AW since birds are used as a surrogate for reptiles. Whether the AW would directly consume bromethalin bait is uncertain. The probability of a snake, which typically consumes live prey, consuming rodenticide bait pellets or Talpirid ® mole bait is believed to be low, although this has not been confirmed by research. Besides direct effects from possible consumption of the bait, the AW and the SMHM could incur indirect effects from effects on other birds, reptiles, and terrestrial-phase amphibians which may directly ingest the bait.

Direct acute effects from primary exposure of the AW to bromethalin bait were evaluated by assuming an individual directly consumes a bait product containing bromethalin at its daily ingestion rate. Bait with two concentrations of bromethalin were assessed, 0.01% (the highest concentration on rodenticide bait) and 0.025% (the concentration in bait for mole control). The average daily food intake rate was estimated using the following allometric equation for insectivorous reptiles (Nagy, 1987 as cited in USEPA, 1993):

$$FI = 0.013\ W^{0.773}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the reptile in g.

To represent the full range of bodyweights of juvenile and adult AW, food ingestion rate was calculated for reptiles weighing 2, 20, and 800 g. These calculations yield FI values of 0.022, 0.13, and 2.3 g/d for small, medium and large whipsnakes, respectively. The FI values were then converted into estimated daily doses using the following equation:

Dose = FI x %AI x (1/W) x 10^4

Where:
Dose is the dose of bromethalin (mg-ai/kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

Finally, acute risk quotients were calculated by dividing the expected dose of bromethalin (mg-ai/kg-bw) by the acute oral LD_{50} value for the northern bobwhite, 4.56 mg-ai/kg-bw (Table 4-3).

Dietary-based risk quotient was also calculated based on subacute dietary LC_{50} value for the northern bobwhite. The 8-day avian dietary LC_{50} for the northern bobwhite is 21 mg ai/kg-Preliminary RQs were calculated by dividing the bromethalin concentration in the bait by this LC_{50} value. However, since birds have a considerably greater energy demand than reptiles, they consume considerably more food relative to body weight than reptiles do. Therefore, the preliminary RQ that directly compares the bromethalin concentration in the bait to the dietary LC_{50} is conservative. Exposure, and thus risk, is directly proportional to the intake of bait, which in this case is estimated by the daily food ingestion rate (FI). Therefore, convert the preliminary (avian) RQ to a reptile RQ, the preliminary RQ was multiplying by the ratio of the predicted FI of the AW divided by the FI of the bobwhite quail. The later was determined by feed consumption and body weight measurements made in the study. In the bobwhite subacute dietary study (MRID 00086744), the mean food consumption rate for control birds was 5.4 g/bird/day and the mean body weight was 20.5 g, giving a FI of 263 g/kg-BW. The adjustment factors for 2, 20, and 800 g snakes were 0.042, 0.025, and 0.011, respectively. The adjusted dietary based RQs for reptiles are given in Table 5-1.

For example, consider the estimation of the dietary RQ from consumption of a small 2-g snake consuming rodent control bait. The dietary concentration is equal to the bromethalin concentration in the bait, which is 0.01% or 100 mg ai/kg-diet. The preliminary (avian) RQ is calculated by dividing this value by the avian subacute dietary LC_{50}, 21 mg ai/kg-diet. This yields a preliminary RQ of 4.76. The FI for a reptile of this size, as estimated from the allometric equation shown above, is 11.1 g/kg/day. The mean food consumption rate of the northern bobwhite in the dietary study was 5.4 g. Dividing this value by the mean body weight of birds in the study (0.0205 kg) yields a FI for the quail of 263 g/kg/day. Thus, the adjustment factor is the ratio of these two FI values, 11.1 divided by 263, which equals 0.0422. Multiplying the preliminary RQ (4.76) by the adjustment factor (0.0422) yields the estimated dietary RQ for the AW of 0.20.

Acute RQs for acute toxicity to reptiles are given in Table 5-1. These RQs represent risk of direct effects to the AW from direct consumption of bromethalin bait. They are also applicable to indirect effects to this species mediated through adverse effects to reptiles and terrestrial-phase amphibians which serve as prey for the AW.

Table 5-1. Acute RQs for Direct Effects to the AW from Consumption of Bromethalin Bait

Size (bodyweight)	Bait Type	%AI	FI[1] (g/d)	Dose (mg ai/kg-BW)	Acute Dose-Based RQ[2]	Acute Dietary-Based RQ[3]
Small (2 g)	Rodent control	0.01	0.022	1.11	0.24	0.20
	Mole control	0.025	0.022	2.77	0.61	0.50
Medium (20 g)	Rodent control	0.01	0.13	0.65	0.14	0.12
	Mole control	0.025	0.13	1.65	0.36	0.30
Large (800 g)	Rodent control	0.01	2.3	0.29	0.06	0.05
	Mole control	0.025	2.3	0.71	0.16	0.13

[1] Daily food ingestion rate based on an allometric equation for insectivorous reptiles.
[2] Based on the FI and the northern bobwhite oral LD_{50} of 4.56 mg/kg-bw
[3] Based on the %AI of the bait and the northern bobwhite dietary LC_{50} of 21mg/kg-diet.

Indirect risk posed to the SMHM mediated by toxic effects to birds was assessed using an approach similar to that used for the AW, except the allometric equation for food ingestion rate (FI) was for birds rather than for reptiles. Risk was again assessed for bait with bromethalin concentrations of 0.01% (rodenticide bait) and 0.025% (bait for mole control). The average daily food intake rate was estimated using the following allometric equation for birds (Nagy, 1987 as cited in USEPA, 1993):

$$FI = 0.648\ W^{0.651}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the reptile in g.

Risk was assessed for birds of the standard default weights of 20, 100, and 1000 g, representing small, medium, and large birds. These calculated FI values for these weight classes were 4.56, 13.0, and 58.2 g/d, respectively. The FI values were then converted into estimated daily doses using the following equation:

$$Dose = FI \times \%AI \times (1/W) \times 10^4$$

Where:
Dose is the dose of bromethalin (mg-ai/kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

Finally, acute RQs were calculated by dividing the expected dose of bromethalin (mg-ai/kg-bw) by the acute oral LD_{50} value for the northern bobwhite, 4.56 mg-ai/kg-bw (Table 4-5).

Because the SMHM makes use of bird nests for nesting sites, they may be indirectly affected by adverse effects on bird populations. Dietary-based RQs for birds which consume bromethalin bait were also calculated by simply dividing the concentration of bromethalin in the bait by the subacute dietary LC_{50} value for the northern bobwhite (21 mg ai/kg-diet). The bromethalin

concentrations in the bait, when expressed as parts-per-million (mg-ai/kg), are 100 for rodenticide bait and 250 for mole-control bait. Therefore, the dietary RQs for indirect effects resulting from toxicity to birds are 4.8 for rodenticide bait and 11.9 for mole-control bait.

RQs for indirect effects to the SMHM mediated through acute toxic effects on birds are given in Table 5-2.

Table 5-2. RQs for Indirect Effects to the SMHM Mediated through Toxicity to Birds from Consumption of Bromethalin Bait

Size (bodyweight)	Bait Type	%AI	FI[1] (g/d)	Dose (mg/kg-ai)	Dose-based Acute RQ[2]	Diet-based Acute RQ[3]
Small (20 g)	Rodent control	0.01	4.56	22.8	5.00	4.8
	Mole control	0.025	4.56	56.9	12.5	11.9
Medium (100 g)	Rodent control	0.01	13.0	13.0	2.85	4.8
	Mole control	0.025	13.0	32.5	7.12	11.9
Large (1000 g)	Rodent control	0.01	58.2	5.82	1.28	4.8
	Mole control	0.025	58.2	14.5	3.19	11.9

[1] Daily food ingestion rate.
[2] Based on the FI and the northern bobwhite oral LD_{50} of 4.56 mg/kg-bw
[3] Based on the %AI of the bait and the northern bobwhite dietary LC_{50} of 21mg/kg-diet.

No chronic avian risk quotients could be calculated because toxicity data on the chronic effects of bromethalin to birds are not available.

Because the acute risk quotients for reptiles exceed 0.1, the LOC for listed species, use of bromethalin has the potential to cause direct and indirect effects to the AW. Additionally, since the acute RQs for birds exceeded the non-endangered LOC of 0.5, the use of bromethalin also has the potential to cause indirect effects to the SMHM through a reduction of nest sites resulting from adverse effects incurred on birds.

5.1.2.b. Mammals

Risk quotients were calculated to assess risk to small mammals which directly consume bromethalin bait. These risk quotients evaluate potential direct acute effects to the SMHM from consumption of bromethalin bait. They also evaluate potential for indirect effects to both the SMHM and the AW, as the SMHM makes use of abandoned nest of other small mammals, and the AW preys upon small mammals. Bait with two concentrations of bromethalin were modeled, 0.01% (the highest concentration on rodenticide bait) and 0.025% (the concentration in bait for mole control). The small mammals were assumed to consume their average daily food intake in the form of the bait. The average daily food intake rate was estimated using the following allometric equation:

$$FI = 0.621\ W^{0.564}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the rodent in g.

This food ingestion rate was calculated for a 10-g mammal, which represents the average weight of the SMHM (USFWS, 1984), and a 20-g mammal, which is representative of a typical small mammal on which the AW might prey. The 20-g mammal also represents a small mammal that might build a nest which the SMHM might use. These calculations yield a FI of 2.28 g/d for the SMHM and 3.36 g/d for the 20-g small mammal. The FI values were then converted into estimated daily doses using the following equation:

$$\text{Dose} = \text{FI} \times \%\text{AI} \times (1/\text{W}) \times 10^4$$

Where:
Dose is the dose of bromethalin (mg-ai/kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

Finally, acute dose-based risk quotients were calculated by dividing the expected dose of bromethalin (mg-ai/kg-bw) by the acute oral LD_{50} value for the rat, 2.59 mg-ai/kg-bw (Table 4-7). Results of these calculations are presented in Table 5-3. No acute dietary-based RQs were calculated for mammals because no acute dietary toxicity data were available.

Chronic risk was evaluated by comparing the concentration of bromethalin in the bait products to the lowest NOAEC for chronic effects related to reproduction, growth, or survival that was observed in chronic rat toxicity studies. Concentrations of bromethalin in the bait are 100 mg-ai/kg bait for rodent control and 250 mg-ai/kg bait for mole control. The lowest chronic NOAEC was 3.3 mg-ai/kg diet (from Table 4-10). Therefore, the chronic RQs for mammals are 30.3 for rodenticide bait and 75.8 for mole-control bait.

RQs for acute and chronic effects to mammals are presented in Table 5-3. These RQs represent direct risk to the SMHM from consumption of bromethalin bait. They also represent risk of indirect effects to the SMHM and the AW mediated through effects on small mammals.

Table 5-3. RQs for Acute and Chronic Effects to Mammals from Consumption of Bromethalin Bait

Mammal (bodyweight)	Bait Type	%AI	FI[1] (g/d)	Dose (mg/kg-bw)	Acute RQ[2]	Chronic RQ[3]
SMHM (10 g)	Rodent control	0.01	2.28	22.8	8.9	30.3
	Mole control	0.025	2.28	57.0	22.2	75.8
Small mammal (20 g)	Rodent control	0.01	3.36	16.8	6.6	30.3
	Mole control	0.025	3.36	42.0	16.4	75.8

[1] Daily food ingestion rate.
[2] Based on the FI and the rat acute oral LD_{50} of 2.57 mg/kg-bw
[3] Based on %AI of the bait and the rat NOAEL of 3.3 mg/kg-diet.

Because the acute RQs exceed 0.1, the LOC for acute effects to listed species, and the chronic RQs exceed 1, the LOC for chronic effects to listed species bromethalin, use of bromethalin has the potential to directly affect the SMHM. Additionally, since the acute and chronic RQs for a 20-g small mammal exceeded the LOCs for nonlisted species, use of bromethalin has the potential to cause indirect effects to both the SMHM and the AW.

5.1.2.c. Terrestrial Invertebrates

Risk was not assessed for terrestrial invertebrates because data on the toxicity of bromethalin to terrestrial invertebrates are not available. In the absence of data, the Agency assumes that the potential exists for bromethalin to adversely affect terrestrial invertebrates. Adverse effects on terrestrial invertebrate potentially could cause indirect effects to the AW, which diet includes terrestrial invertebrates. However, exposure to invertebrates to the vertebrate control bait is not expected to be enough to have significant impact on invertebrate populations or to cause significant food-chain effects to the AW (Section 2.9.2).

5.1.2.d. Terrestrial Plants

Risk was not assessed for terrestrial plants because data on the toxicity of bromethalin to terrestrial plants are not available. The mode of action of bromethalin is uncoupling of oxidative phosphorylation. Since oxidative phosphorylation occurs similarly in the mitochondria of almost all eukaryotic organisms, this mode of action is relevant to plants as well as animals. Therefore bromethalin could be toxic to plants as well as animals.

In the absence of data, indirect effects to the assessed species through effects on vegetation, resulting in habitat modification, is assumed to be possible. However, any such impacts would be expected to be limited in spatial extent, likely occurring only in the immediate vicinity of the bait placement. Overall, any toxicity to terrestrial plants is expected to have minimal impact to the assessed species and to the quality of their habitat.

5.1.3. Secondary Exposures to the AW

The AW is likely to be exposed to bromethalin residues from secondary exposure, that is from consumption of prey that have consumed bromethalin bait. As discussed in Section 3.3.2, the AW is capable of consuming all of the target species of small mammals of bromethalin bait products, including rats, mice, and moles. Therefore, risk assessments for secondary exposure were conducted for a snake which feeds on a Norway rat (*Rattus norvegigus*), a house mouse (*Mus musculus*), and a broad-footed mole (*Scapanus latimanus*, a mole native to central California). These species were assumed to have consumed bromethalin bait at their daily ingestion rate. The rat and the mouse were assumed to have consumed rodenticide bait with a bromethalin concentration of 0.01%, whereas the mole was assumed to have consumed bait with a bromethalin concentration of 0.025%. Assumed body weights of these prey species were 485 g for the Norway rat, 23 g for the house mouse, and 140 g for the broad-footed mole. These represent the high end of the range for these species to represent the highest potential exposure of bromethalin from secondary exposure. The body weight of the snake was set at the weight of the

minimum sized animal which would be predicted to be able to consume prey of the assumed size, as described in 3.3.2.

The average daily food intake rates of the three assumed prey species were estimated using the following allometric equation for mammals:

$$FI = 0.621\ W^{0.564}$$

Where FI is the food intake rate in g/d, and W is the bodyweight of the rodent in g.

The calculated FI for the Norway rat, house mouse, and broad-footed mole were 20.3, 3.64, and 10.1 g, respectively. The FI values were then converted into estimated ingested doses of bromethalin using the following equation:

$$Dose = FI \times \%AI \times (1/W) \times 10^4$$

Where:
Dose is the dose of bromethalin (mg-ai/kg-bw)
FI is the food ingestion rate (g)
%AI is the percent active ingredient in the bait
W is the body weight (g)

To assess the maximum exposure that an AW could receive through secondary exposure, 100% of the active ingredient which was ingested by the small mammal prey was assumed to be present in the animal when it was consumed by the snake. This is not implausible because a snake could prey upon the small mammal very soon after it has ingested the bait, with all of the bromethalin contamination present in the ingesta within the gastrointestinal tract of animal, before it has had a chance to metabolize or excrete any of it. Thus the amount of active ingredient the prey was assumed to ingest was also the dose, in mg, which the AW was assumed to ingest. This dose was then divided by the assumed body weight of the snake to convert the dose into units of mg ai/kg BW. Finally, the acute secondary exposure risk quotients were calculated by dividing the predicted dose of bromethalin (mg-ai/kg-bw) by the acute oral LD_{50} value for the rat, 2.59 mg-ai/kg-bw (Table 4-6). Results of these calculations are presented in Table 5-4. No acute dietary-based RQs were calculated because no acute dietary toxicity data were available for mammals.

Chronic risk was evaluated with risk quotients. The chronic mammal studies measured toxicity in animals which received a daily dose of bromethalin every day for an extended exposure period. This is very different than an AW, which after receiving a single dose from preying on a small mammal, would not likely feed again for several weeks. Thus, even if the snake would feed exclusively on small mammals that ingested bromethalin prey, it would receive only one dose every several weeks. The chronic rat studies do demonstrate, however, that bromethalin can cause sublethal effects on growth and reproduction at exposure levels considerably lower than those which cause mortality. Thus, the chronic risk quotient would certainly be greater than the acute risk quotients. Because all of the risk scenarios for secondary poisoning produced risk

quotients above 1, it is certain that all of the chronic risk quotients also exceed 1, the LOC for chronic risk.

Table 5-4. RQs for Acute Effects to the AW from Consumption of a Small Mammal which Ingested Bromethalin Bait

Bait Type	Prey Species	Assumed weight of AW	%AI in Bait	Prey FI[1] (mg/d)	Dose (mg ai/kg BW)	Acute RQ[2]
Rodent control	Norway rat (485 g)	322 g	0.01	20.3	6.11	2.4
	House mouse (23 g)	18.6 g	0.01	3.64	19.6	7.6
Mole control	Broad-footed mole (140 g)	101 g	0.025	10.1	25.0	9.7

[1] Daily food ingestion rate.
[2] Based on the dose in the ingested prey and the rat acute oral LD_{50} of 2.59 mg/kg-bw

Because the acute RQs for secondary exposure exceed 0.1, the LOC for acute effects to listed species, use of bromethalin has the potential to directly affect the AW by way of secondary exposure.

To further characterize the secondary risk of bromethalin, calculations were made to estimate the amount of time required for bromethalin residues in the exposed prey to decline to a level where the risk to the AW, as expressed by the RQ, no longer exceeds 0.1, the LOC for acute risk to listed terrestrial species. These calculations were made based on elimination of the bromethalin from a living small mammal. Because whipsnakes locate prey by sight, not scent, they would not be expected to consume the carcass of a dead animal. Thus, the persistence of residues in the carcass of dead animals is not relevant to the risk of secondary poisoning to the AW. The rate of terminal elimination of bromethalin measured in a rat metabolism study was used to represent the decline of bromethalin residues in a living small mammal. Van Lier and Cherry (1988, MRID 004724) determined the half-life of terminal elimination was 5.62 days, making the rate constant (k) 0.123 days. The concentration of bromethalin in the prey would need to decline by a factor of 10 times the RQ for the RQ to decrease to 0.1. (For example, the RQ for the snake eating the rat is 2.3. The RQ is directly proportional to the concentration of bromethalin in the rat. Therefore, the concentration in the rate would need to decrease 23 times for the RQ to be reduced to 0.1.) Assuming first order degradation, the time required for the concentration to decline by this factor, making the RQ equal 0.1, is given by the following equation:

$$t = -\ln(1/10Q) / k$$

Where:
t = time in days
Q = the risk quotient
k = the rate constant.

For a snake eating a live animal, bromethalin concentration in the prey is expected to remain at a level that would pose a significant risk (i.e., yield an RQ greater than or equal to 0.1) for between 26 and 37 days. That duration would only be relevant for prey that consume a sublethal dose, as toxicology studies show that animals that receive a lethal dose typically do not live for more than two or three days. If the prey animal ingests a lethal dose, then the risk of secondary poisoning is expected remain high for a few days until the animal dies.

5.1.4. Primary Constituent Elements of Designated Critical Habitat

For bromethalin use, the assessment endpoints for designated critical habitat PCEs involve the same endpoints as those being assessed relative to the potential for direct and indirect effects to the listed species assessed here. Therefore, the effects determinations for direct and indirect effects are used as the basis of the effects determination for potential modification to designated critical habitat.

5.2. Risk Description

The risk description synthesizes overall conclusions regarding the likelihood of adverse impacts leading to a preliminary effects determination (*i.e.*, "no effect," "may affect, but not likely to adversely affect," or "likely to adversely affect") for the assessed species and the potential for modification of their designated critical habitat based on analysis of risk quotients and a comparison to the Level of Concern. The final *No Effect/May Affect* determination is made after the spatial analysis is completed at the end of the risk description, Section 5.2.4. In Section 5.2.4, a discussion of any potential overlap between areas where potential usage may result in LAA effects and areas where species are expected to occur (including any designated critical habitat) is presented. If there is no overlap of the species habitat and occurrence sections with the Potential Area of LAA Effects a *No Effect* determination is made.

If the RQs presented in the Risk Estimation (Section 5.1) show no direct or indirect effects for the assessed species, and no modification to PCEs of the designated critical habitat, a preliminary *No Effect* determination is made, based on bromethalin's use within the action area. However, if LOCs for direct or indirect effect are exceeded or effects may modify the PCEs of the critical habitat, the Agency concludes a preliminary *May Affect* determination for the FIFRA regulatory action regarding bromethalin. For this assessment of the use of vertebrate control bait products containing bromethalin, a preliminary *May Affect* determination was made for both the AW and the SMHM. A preliminary *May Affect* determination was also made for adverse effects on the PCE's of the critical habitat of the AW. (Critical habitat has not been designated for the SMHM.) A summary of the risk estimation results are provided in Table 5-5 for direct and indirect effects to the AW and SMHM, and in Table 5-6 for the PCEs of their designated critical habitat.

Table 5-5. Risk Estimation Summary for Bromethalin - Direct and Indirect Effects

Taxa	LOC Exceedances (Yes/No)	Description of Results of Risk Estimation	Assessed Species Potentially Affected
Birds, Reptiles, and Terrestrial-Phase	Non-listed Species: Yes	Risk of acute toxic effects to birds that feed on any	Indirect Effects: SMHM

Taxa	LOC Exceedances (Yes/No)	Description of Results of Risk Estimation	Assessed Species Potentially Affected
Amphibians		bromethalin bait, and to reptiles and terrestrial-phase amphibians which feed on bait used for mole control.	and AW
	Listed Species: Yes (for mole control bait only)	Risk of secondary poisoning from snakes feeding on small mammals which ingested bromethalin bait. Risk of acute toxic effects to small snakes which feed on bromethalin bait for mole control.	Direct Effects: AW
Mammals	Non-listed Species: Yes	Risk of acute and chronic effects small mammals that feed on bromethalin bait.	Indirect Effects: SMHM and AW
	Listed Species: Yes	Risk of acute and chronic effects small mammals that feed on bromethalin bait.	Direct Effects: SMHM

Table 5-6. Risk Estimation Summary for Bromethalin – Effects to Designated Critical Habitat. (PCEs)

Taxa	LOC Exceedances (Yes/No)	Description of Results of Risk Estimation	Species Associated with a Designated Critical Habitat that May Be Modified by the Assessed Action
Birds, Reptiles, and Terrestrial-Phase Amphibians	Non-listed Species: Yes	Risk of acute toxic effects to birds, reptiles, and terrestrial-phase amphibians that feed on bromethalin bait.	AW
	Listed Species: Yes	Risk of secondary poisoning from snakes feeding on small mammals which ingested bromethalin bait. Risk of acute toxic effects to small snakes which feed on bromethalin bait for mole control.	
Mammals	Non-listed Species: Yes	Risk of acute and chronic effects small mammals that feed on bromethalin bait.	AW
	Listed Species: Yes	Risk of acute and chronic effects small mammals that feed on bromethalin bait.	

Following a preliminary "may affect" determination, additional information is considered to refine the potential for exposure at the predicted levels based on the life history characteristics

(*i.e.*, habitat range, feeding preferences, *etc*.) of the assessed species. Based on the best available information, the Agency uses the refined evaluation to distinguish those actions that "may affect, but are not likely to adversely affect" from those actions that are "likely to adversely affect" the assessed species and its designated critical habitat.

The criteria used to make determinations that the effects of an action are "not likely to adversely affect" the assessed species or modify its designated critical habitat include the following:

- Significance of Effect: Insignificant effects are those that cannot be meaningfully measured, detected, or evaluated in the context of a level of effect where "take" occurs for even a single individual. "Take" in this context means to harass or harm, defined as the following:
    - Harm includes significant habitat modification or degradation that results in death or injury to listed species by significantly impairing behavioral patterns such as breeding, feeding, or sheltering.
    - Harass is defined as actions that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavior patterns which include, but are not limited to, breeding, feeding, or sheltering.
- Likelihood of the Effect Occurring: Discountable effects are those that are extremely unlikely to occur.
- Adverse Nature of Effect: Effects that are wholly beneficial without any adverse effects are not considered adverse.

A description of the risk and effects determination for each of the established assessment endpoints for the assessed species and their designated critical habitat is provided in Sections 5.2.1 through 5.2.2. The effects determination section for each listed species assessed will follow a similar pattern. Each will start with a discussion of the potential for direct effects, followed by a discussion of the potential for indirect effects. These discussions do not consider the spatial analysis. For those listed species that have designated critical habitat, the section will end with a discussion on the potential for modification to the critical habitat from the use of bromethalin. Finally, in Section 5.2.4, a discussion of any potential overlap between areas of concern and the species (including any designated critical habitat) is presented. If there is no overlap of the species habitat and occurrence sections with the Potential Area of LAA Effects a No Effect determination is made.

5.2.1. Alameda Whipsnake

5.2.1.a. Direct Effects

The primary risk of direct effect of bromethalin bait on the AW is believed to be secondary poisoning. Secondary poisoning may occur if a whipsnake consumes small mammals that feed directly on the bait. The AW diet includes small mammals, and it may consume any of the target species that bromethalin bait products are meant to control (rats, mice, and moles). Mice and

moles are easily within the size of prey that the AW could consume. Calculations of maximum prey size indicate that a large adult whipsnakes would also be able to prey upon an adult Norway rat or roof rat (see Section 3.3.2). Whether a whipsnake would scavenge upon a dead mammal that was killed by bromethalin bait is unknown, but since rats and mice poisoned by bromethalin may not die for a few days, considerable opportunity would exist for the snake to prey on a poisoned small mammal before it dies. In fact, small mammals partially incapacitated by bromethalin exposure would likely be attractive prey to the snakes. Sublethal effects of bromethalin include hind-leg weakness, lethargy, ataxia, and loss of righting ability (Table 4-9). These sublethal symptoms likely would make poisoned rodents easier to catch.

Extensive use of bromethalin bait products is believed to be possible in the region where the AW occurs. The counties where the AW occurs (Contra Costa, Alameda, San Joaquin and Santa Clara Counties) include many highly developed and densely populated areas (see Section 5.2.4). Placement of bromethalin rodenticide bait around residential homes, farm buildings, commercial buildings, and recreation buildings in these counties would provide widespread opportunities for the snake to encounter prey poisoned by bromethalin bait. The snakes may occur in close proximity to these buildings, for example by living in the crawlspace underneath a home, or in or under a utility shed or agricultural building. Since rodenticide bait would most likely be used in areas where high rodent populations exist, and the dense abundance of rodents in these areas may attract the snake. The snakes would also be expected to occur in and around areas where bromethalin bait may be applied for mole control. Placement of mole bait is not restricted to around buildings, and thus may occur almost anywhere within the habitat of the AW. The AW is known to use small mammal burrows for shelter and foraging, and thus would be expected to enter into the underground runways of the moles where the bait is placed. Whipsnakes which enter mole runways may forage on moles that have ingested bromethalin bait.

The restriction of the placement of the rodenticide bait to within 50 ft of exterior walls of buildings is not expected to protect the AW exposure to bromethalin. There is no reason to believe that this snake would not venture near buildings, especially when one considers the term “buildings” includes buildings of all types, not just homes. Furthermore, the acute rat toxicity studies showed that small mammals which feed on the bromethalin bait may not die for two or three days. Contaminated small mammals may travel considerable distance away from the buildings and bait stations during that time. Therefore, the AW may be exposed through secondary exposure even if they do not forage near buildings. Finally, as stated previously, use of the registered mole control bait (Talpirid ®) is not restricted to areas near buildings.

Risk quotients for secondary poisoning show that the amount of active ingredient that a rat, mouse, or mole ingests would pose a risk of acute toxicity to a whipsnake that feeds on it (acute RQs: 2.4-9.7). An assessment was also conducted to predict the length of time that toxicity in a prey animal would remain at levels that would yield a RQ above the LOC of 0.1, and thus may pose a risk of secondary poisoning to the AW. This assessment found that bromethalin levels in a living prey animal potentially could remain a risk for 26 to 37 days after the bait is ingested. However, since laboratory studies show that mammals that die from bromethalin poisoning usually die within two or three days, prey which ingest a lethal dose would not be expected to remain alive for this long. Still, risk of secondary hazard would likely be high while the prey is intoxicated and immobilized by bromethalin poisoning, but remains alive. Laboratory acute

toxicity studies show that rodents generally live no more than two or three days after ingesting a lethal dose of bromethalin. Small mammals exposed to bromethalin may be immobilized during this time, showing symptoms of bromethalin toxicity such as limb weakness and tremors. This could make them attractive prey which a snake could easily catch. Once the prey animal dies, it is not expected to pose a significant risk of secondary poisoning to the AW. Whipsnakes hunt by sight and are attracted to prey by movement, and thus would be unlikely to consume a dead carcass.

Risk quotients indicate even greater risk of chronic toxic effects for any snake that ingests the contaminated prey and survives the acute toxicity (chronic RQs: 61-250). While not assessed, other nontarget species may ingest bromethalin bait and then may be preyed upon by the AW. Consumption of birds, reptiles, and terrestrial-phase amphibians which ingested bromethalin bait also would likely pose a risk of secondary poisoning to the AW.

Based on the RQs and the LD_{50} and slope of the dose-response curve in the acute oral toxicity study, calculations were made to determine the probability that a particular individual would be killed by the dose predicted for an AW consuming a contaminated small mammal. The individual probability of death is very high (1 in 1.007) and almost certain for a snake preying on a contaminated mouse or rat (1 in 1.000 when rounded to 4 significant figures).

While the results of the risk assessment indicate that nontarget reptiles like the AW would be susceptible to secondary poisoning from bromethalin, this risk has not been confirmed by documented incidents or by laboratory or field studies. As discussed in Section 4.5, no wildlife mortality incident has been documented in which primary or secondary exposure to bromethalin was identified as the cause. While this lack of confirmatory incident evidence makes the *Likely to Affect* conclusion less certain, it does not negate this conclusion. There are many reasons why poison incidents may occur but do not get reported and/or adequately investigated to identify the cause, therefore, a lack of reported incidents cannot be used to conclude a lack of risk (Vayas, 1999. This is particularly true for assessments of risks to a reptile since poisonings incidents involving reptiles are rarely observed or reported.

Only two studies are available which attempted to evaluate the potential of secondary poisoning from consumption of rodents which are exposed to bromethalin bait. Van Lier (1981) observed no mortality in dogs which were fed 600 g of ground meat obtained from rats which had in fed upon bromethalin bait for one day (see discussion in 4.3.2.c). The bromethalin bait used in the study contained 0.005% bromethalin. Spaulding et al. (1985) found no evidence of mortality of nontarget animals when they conducted carcass searches of areas where 0.005% bromethalin bait was applied to control the Norway rat and house mouse (see discussion in Section 4.5). However, the findings of these studies are considered uncertain and inconclusive because too little detail is available on the study methodologies and test designs to determine if they were scientifically valid. Even if they are scientifically valid, the results would not provide adequate evaluation of risk for this assessment because the bait used in these studies contained only 0.005% bromethalin. Products are registered for both rodent control and for mole control which contain at least double this concentration of active ingredient. Furthermore, neither study provides information on secondary risk of bromethalin to snakes. The laboratory study was done with dogs which may respond very differently than reptiles. The field study was an efficacy

study which incorporated carcass searches that were designed to locate dead rodents and therefore may not have been effective at finding poisoned reptiles. Additional research investigating the risk of secondary poisoning of currently registered bromethalin products to snakes would be needed to confirm or refute the secondary poisoning risks identified by this risk assessment.

Risk quotients indicate that direct consumption of bromethalin bait by the AW also would pose an acute risk to the AW. Acute RQs for a reptile that directly ingested the bait ranged from 0.05-0.24 for rodenticide bait and 0.13-0.61 for mole control bait. This risk is much less certain than the secondary exposure risk, however, because it is uncertain if the AW would feed directly on the baits. The pellets or blocks of rodenticide baits would not be attractive food to an AW. The bait used for mole control (Talpirid ®) may be more attractive because it is made of impregnated material that is shaped to mimic a worm or a grub. Still, it seems unlikely that a snake would be attracted to this bait since it does not provide the movement, odor, or heat cues that snakes normally use to identify prey.

In conclusion, the weight of evidence justifies the conclusion of *Likely to Affect* for the use of bromethalin to adversely affect the survival and reproduction of the AW. This conclusion is based primarily risk from direct effects of the snake exposure to bromethalin, in particular from secondary exposure that may occur from consumption of poisoned prey.

5.2.1.b. Indirect Effects

The risk assessment also identified the potential for bromethalin use to cause indirect effects on the AW. These indirect effects would be mediated through direct toxic effects on birds, small mammals, terrestrial-phase amphibians, and other reptiles, causing reduction in their abundance. Reduced abundance of these species would indirectly affect the AW by reducing the availability of prey, thereby possibly jeopardizing the ability of the species to meet its energy demands for survival and reproduction. Furthermore, since the AW uses small mammal burrows for cover and foraging (USFWS, 2006), reduced small mammal abundance may adversely affect the habitat of the AW by reducing the abundance of these burrows. These indirect effects, however, are expected to have less impact on the success of this species than the direct toxicity effects would. Mortality caused by the use of these products is not expected to be great enough to cause significant declines in the populations of small mammal species other than possibly the four target species occurring in this region (the Norway rat, roof rat, the house mouse, and the broad-footed mole). Even for the target species, effects on abundance would likely be localized to areas around buildings where bait stations are placed for rodent control, and near ornamental lawns and gardens where bait is placed for mole control. This limited area of use would make widespread effects on small mammal populations unlikely. Finally, the majority of the diet of the AW is likely to be composed of nontarget prey species which would not be affected much by use of bromethalin bait. Lizards in particular are believed to be the most important prey item of whipsnakes (USFWS, 2005). Lizards generally feed upon insects and other terrestrial arthropods and would not likely consume rodent bait. They also would not likely consume mole bait because they would not likely forage in the underground runways where this bait must be placed.

The use of bromethalin in bait for rodent and mole control is not expected to result in significant exposure to terrestrial plants, and therefore the risk of indirect effects to the AW mediated through modification of vegetation is expected to be discountable. Clearly there is no spray drift exposure to plants from this use. Exposure to terrestrial plants would be limited to absorption through the roots by plants growing in soil contaminated by the bait. Only plants growing in the immediate vicinity of placed bait would be expected to be exposed to contaminated soil. Thus, the area where terrestrial plants may be exposed and potentially adversely affected is expected to be very small relative to home range of a snake. Thus any damage that might occur to plants would not be expected to cause significant vegetative damage which would significantly deteriorate the quality of the habitat of this species. Additionally, the amount of residues that would leach from bromethalin bait is expected to be small because bromethalin has very low water solubility (0.002 mg/L) and low to moderate leachability (K_d = 39-168)]. Furthermore, bait products used for rodent control are normally either placed within a plastic bait station that would minimize contact with rain water, or are formulized into weather-resistant blocks or tablets which do not readily deteriorate. Therefore, risk of indirect effects of bromethalin to the AW mediates through damage to terrestrial plants is considered negligible.

5.2.2. Salt Marsh Harvest Mouse

5.2.2.a. Direct Effects

As discussed in Section 2.3, the U.S. Fish and Wildlife Service published a biological opinion in March of 1993 that concluded that use of bromethalin in and around buildings to control the Norway rat, roof rat, and house mouse jeopardizes the continued existence of the salt marsh harvest mouse. The use of registered products of bromethalin to control rodents has not changed appreciably since this opinion was issued. Use of bromethalin in bait to control moles was not considered in the previous biological opinion, but would only increase the potential risk posed by bromethalin use to this species. Furthermore, this previous opinion is in agreement with the conclusion of the risk assessments conducted in this document.

Being a product that is used to kill rodents, it is not surprising that our risk assessment concluded that direct dietary exposure to bromethalin bait may be lethal to the SMHM. The acute RQs for SMHM ingesting bromethalin bait is 8.9 for products used to control rodents and 22.2 for the product used to control moles. Since females were more sensitive than males in the acute oral toxicity study, the RQs are higher if based on toxicity to females. The RQs for female rodents is 10.8 for products used to control rodents and 26.9 for the product used to control moles. RQs of these magnitudes clearly indicate that ingestion of this bait may be lethal to this species. An analysis was made based on these RQs and the slope of the dose-response curve in the acute oral toxicity study to determine the probability that a particular individual would be killed by the predicted dietary dose associated with these RQs. The probability of death is almost certain (1 in 1.000 when rounded to 4 significant figures).

Ingestion of only a small amount of bait may be lethal to the SMHM. Based on the rat acute oral LD_{50}, a 10-g SMHM would only need to ingest only 25.9 µg of bromethalin to reach the median lethal dose. This is equivalent of ingesting 0.259 g of rodenticide bait (0.01 % AI) or 0.104 g of bait used for mole control (0.025% AI). Even if the mouse ingests less than these amounts, it

could still suffer sublethal effects. Sublethal effects of bromethalin to small mammals are related its neurotoxicity and includes hind leg weakness, lethargy, shortness of breath (dyspnea), and tremors (Table 4-9). These sublethal effects clearly could have an adverse effect on survival by impair the animal's ability to forage and avoid predation. Furthermore, chronic studies with small mammals indicate that sublethal exposure to bromethalin may suppress the immune system. Rats exposed to 10 mg/kg bromethalin in their diet had increased incidents of upper respiratory infections (MRID 00086731). Also, in a developmental toxicity study with rabbits, one rabbit exposed to 16.5 mg/kg bromethalin in its diet died from a pneumonia infection, and a second rabbit at the same treatment level developed an upper respiratory infection (MRID 00101545).

No incidents have been reported that have been linked death of a nontarget small mammals from exposure to bromethalin. While this fails to confirm the risk predicted by the risk assessment, the lack of reported incidents does not refute risk.

The risk of bromethalin to the SMHM is largely determined by the likelihood that individuals of this species will encounter bromethalin bait products. As bromethalin bait is used for control of commensal pest rodents and moles in primarily nonagricultural settings, the use of bromethalin bait is expected to correlate with human development and population density. SMHM occurs in heavily developed areas in central California around the San Francisco Bay estuary. Its habitat is near the major metropolitan areas of San Francisco, Oakland, San Mateo, Palo Alto, San Rafael, and Vallejo. A spatial analysis of the species occurrence, using the "developed" data of the NLCD, shows that the species occurrence is associated with highly developed areas (Fig. 5-1). Therefore, the Agency expects there is widespread opportunity for this species to encounter placement of bromethalin bait.

The SMHM inhabits middle and upper regions of salt marshes of the San Francisco Bay estuary. This species would therefore be vulnerable to exposure to bait placed in and near marsh habitats along the coastline of the estuary and its tributaries. Bromethalin rodent control products may be used around any type of building, and many types of buildings may occur near marshes. Examples of buildings that could occur near marshes where rodent bait may be used include homes, restaurants, commercial businesses, port terminals, and boat houses. Bromethalin rodent bait may also be used to control rodents in sewers. Some storm sewers likely drain into salt marsh in this area. This mouse possibly may enter into these storm sewers, and thus encounter rodenticide bait placed within those sewers. Bromethalin bait used for mole control would not likely be used within a salt marsh, but could be used in lawns and gardens immediately adjacent to the marshes. In conclusion, the Agency believes that there is high probability that bromethalin bait may be placed in areas accessible to the SMHM.

5.2.2.b. Indirect Effects

Indirect effects of bromethalin on the SMHM are not expected to be significant. As this species is herbivorous, prey loss is not a significant concern. Reduction of food or physical habitat characteristics through adverse effects on terrestrial and aquatic plants are believed to be discountable. The toxicity of bromethalin to terrestrial plants is unknown. However, little bromethalin is expected to leach out of the bromethalin bait into soil, and thus little exposure to

terrestrial plants is expected. Exposure to terrestrial plants is expected to be minor and restricted to very small areas in the immediate area of placed baits. Overall impacts to the habitat of the SMHM are expected to be negligible. As discussed in Section 2.10.1.a, transport of residues from the bait into aquatic habitat is also expected to be negligible. Therefore, adverse effects to aquatic plants in the salt marsh habitat of the SMHM are considered discountable.

Use of bromethalin bait could reduce the abundance of small mammals in the area near bait placement, especially the abundance of the target species (Norway rat, roof rat, and house mouse). Since the SMHM may utilize abandoned nests of other small mammals for nest sites, some reduction of nest sites is possible. This species may also use abandoned bird nests for nest sites. Birds are not likely to directly ingest much of the bromethalin bait, and thus significant reduction in bird populations or bird nest abundance is not expected.

5.2.3. Modification of Designated Critical Habitat

Critical habitat has been defined for the AW, but not the SMHM. As discussed above, the potential for bromethalin use to adversely modify the critical habitat of the AW stems primarily from reduction of prey species and potential reduction of small mammal burrows. Use of rodenticide and mole-control bait certainly has the potential to adversely affect the abundance of small mammals within the critical habitat. Since the AW preys on small mammals (along with other types of terrestrial vertebrates and invertebrates), adverse effects on small mammal communities could adversely affect the habitat by reducing the abundance of prey. Birds, reptiles, terrestrial-phase amphibians, and terrestrial arthropods are also prey of the AW. Reductions in the abundance of these types of prey are also possible, although less certain because the likelihood that these types of animals would consume bait designed for rodents and moles is uncertain. In addition to prey effect, AW makes use of small mammal burrows for refuge and foraging. Therefore, reduction of small mammal abundance could adversely affect the critical habitat by reducing the availability of this important habitat resource.

As discussed in Section 5.2.1.b, use of bromethalin in bait products to rodent and mole pests is not expected to result in significant exposure to plants. Bait placement placed by hand in specific bait stations around buildings and in mole runways. It cannot be broadcasted. Any exposure to plants would be minor and limited to the area immediately around the bait placement.

5.2.4. Spatial Extent of Potential Effects

Generally, the Agency conducts analysis of the spatial extent of potential LAA effects whenever LOCs are exceeded. This analysis typically is needed to determine where adverse effects may occur in relation to the treated site. This spatial analysis typically determines if the potential area of usage, and the subsequent Potential Area of LAA Effects, overlaps with areas of occurrence and/or critical habitat of the species. However, because bromethalin is a vertebrate pest control that may be used in a wide variety of urban and non-urban areas, the spatial extent of bromethalin cannot be limited to defined areas. The Agency assumes that bromethalin potentially may be used in any area of the state, as any area could potentially be adjacent to some kind of building where bromethalin rodenticide bait may be placed, or in an area where

bromethalin mole control product may be used. Bromethalin use may occur in any of the land use categories that are identified in the NLCD. Therefore, a spatial analysis was not conducted to identify this overlap. All areas where these species occur, and all areas of the critical habitat of the AW, are assumed to lie within the potential use area of bromethalin.

An alternative type of spatial analysis was conducted to characterize the potential use of bromethalin bait products within the region where the assessed species may occur. Since outdoor use of bromethalin bait for rodent control must within 50 ft of the wall of a building, the extent of this use is expected to be highly correlated with human development. The registered mole control product is likely to be used mostly on residential and commercial lawns and ornamental gardens, and likely would also be correlated with human development. Therefore, spatial analyses were conducted in which the occurrence locations of the AW and SMHM were overlaid with a representation of human development. The "Developed" land cover classes of the NLCD were used to represent the intensity of human development. These land cover classes were displayed with gray shading, with darker grays representing areas of more intense development. This layer was overlaid on segments and points that represent the location of the assessed species, and for the AW, the location of its critical habitat. The results of these spatial analyses are shown in Figure 5-1 for the AW and in Figure 2 for the SMHM.

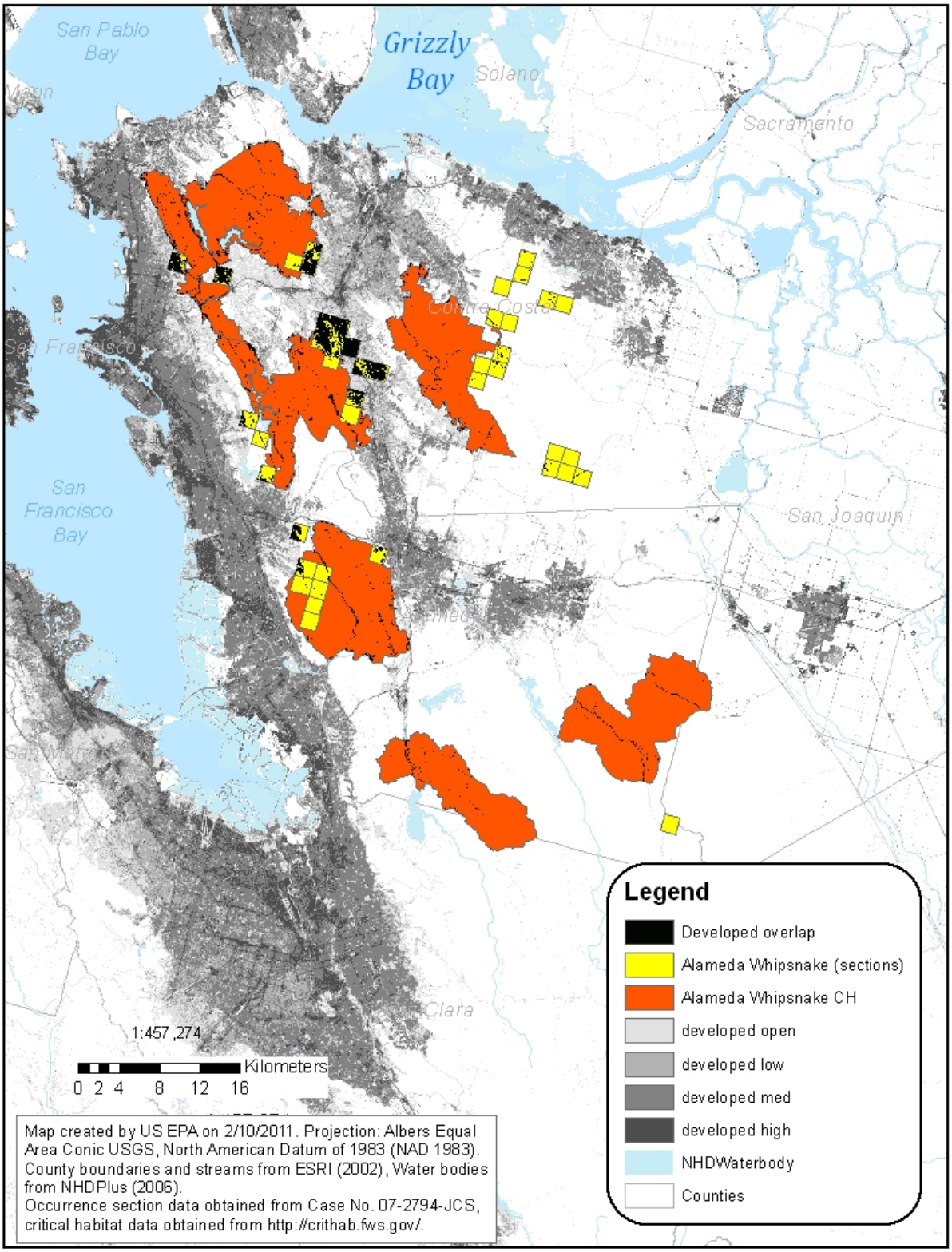


Figure 5-1. Map showing the occurrence of Alameda whipsnake, and its critical habitat, in relation to the intensity of human development.

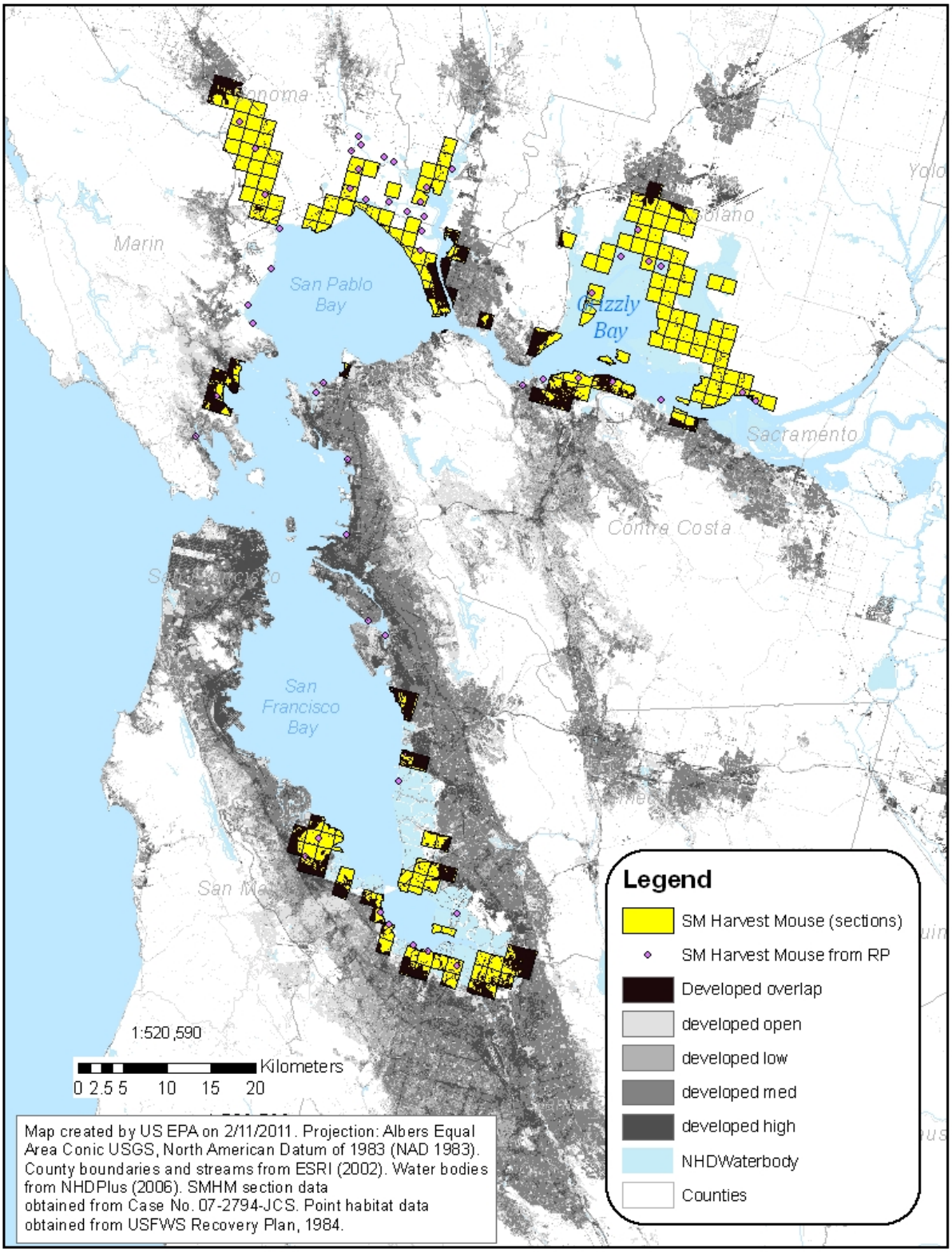


Figure 2-2. Map showing the occurrence of the salt marsh harvest mouse in relation to the intensity of human development.

Areas with higher human development are expected to represent areas where bromethalin bait would be more intensively used and where species would be most vulnerable to exposure to bromethalin. On the scale displayed, the maps have limited usefulness for identifying specific areas of vulnerability. However, the maps do show that both the AW and the SMHM occur in a region of California where development is widespread, and a significant portion of range of both species occurs in areas with moderate to high development. As both species occur in areas where they would be bromethalin bait may be intensively used, both would be susceptible to exposure to bromethalin.

5.3. Effects Determinations

5.3.1. Alameda Whipsnake

The results of this risk assessment indicates that use of bromethalin in baits for vertebrate pest control poses a high risk of acute toxicity to the AW resulting from secondary exposure. Secondary poisoning may occur when the AW preys upon small mammals or other vertebrate prey species which have ingested the bromethalin bait. Further risk to this species would be posed by sublethal behavioral and neurological effects which may result from acute or chronic exposure to bromethalin. Although less certain, some additional risk also may be exist for direct effects from primary exposure to bromethalin bait. Finally, indirect effects are also possible from use of this product reducing the abundance of vertebrate prey, and possibly reducing the availability of small mammal burrows.

Therefore, the Agency makes **"may affect"** and **"likely to adversely affect**" determinations for the AW, and a **habitat modification determination** for its designated critical habitat, based on the potential for direct and indirect effects and effects to the PCEs of critical habitat.

5.3.2. Salt Marsh Harvest Mouse

The results of this risk assessment indicates that use of bromethalin in baits for vertebrate pest control poses a risk of direct effects to the SMHM resulting from acute toxicity. This species has the potential to come into contact with bromethalin bait placed for rodent and mole control. Ingestion of this bait is likely to be lethal to the SMHM. Even if the ingested dose of bromethalin is not lethal, sublethal behavioral and neurological effects may adverse effect the survival of this species. Finally, some risk of indirect effects is possible because use of this product may reduce the abundance of small mammals, which may reduce the availability of nest sites. Therefore, the Agency makes **"may affect"** and **"likely to adversely affect**" determinations for the SMHM based on the potential for direct and indirect effects to this species.

5.3.3. Addressing the Risk Hypotheses

In order to conclude this risk assessment, it is necessary to address the risk hypotheses defined in Section 2.9.1. Based on the conclusions of this assessment, many of the risk hypotheses cannot be rejected, meaning that the stated hypotheses represent potential adverse effects that use of

bromethalin may cause. Specifically the risk hypotheses which cannot be rejected are listed below.

The labeled use of bromethalin within the action area may:

- directly affect the AW and SMHM by causing mortality or by adversely affecting growth or fecundity;
- indirectly affect the AW and SMHM and/or modify the designated critical habitat of the AW by reducing or changing the composition of food supply;
- indirectly affect the AW and SMHM and/or modify their designated critical habitat of the AW by reducing or changing terrestrial habitat in their current range (via reduction in availability of small burrowing mammals burrows used by the AW for cover, or bird and /or small mammal nests used by the SMHM for nest sites).

The risk assessment did indicate that two of the risk hypothesis may be rejected. The two hypotheses which were rejected are that use of bromethalin may:

- indirectly affect the AW and SMHM and/or modify their designated critical habitat of the AW by reducing or changing the composition of the terrestrial plant community in the species' current range;
- indirectly affect the SMHM by reducing or changing the composition of the aquatic plant community in the species' current range, thus affecting primary productivity and/or cover;

Indirect effects mediated through effects on terrestrial and aquatic plant communities were judged to be discountable.

6. Uncertainties

Uncertainties that apply to most assessments completed for the San Francisco Bay Species Litigation are discussed in Attachment I. This section describes additional uncertainties specific to this assessment.

6.1. Exposure Assessment Uncertainties

6.1.1. Terrestrial Exposure Assessment Uncertainties

Uncertainty in the exposure assessment stems mainly from assumption made in the assessment related to the consumption of bromethalin bait by various types of animals. Animals were assumed to consume an amount of bait equal to their predicted daily food ingestion rate. Ingestion of bait is most certain for omnivorous small mammals because the bait is designed to be attractive to rodents and moles. However, small mammals could eat less bait than their average daily ingestion rate, either because they are also feeding on other food sources, or because they exhibit bait shyness. Alternatively, if other food is scarce and they find the bait to

be a very attractive, then they could exhibit gorging behavior, consuming bait in excess of their daily average daily intake rate. The consumption of bromethalin bait by animals other than small mammals is less certainty. No incidents or field studies have shown that species other than small mammals consume the bait. Animals which feed predominantly on live prey, including the AW, may not consume the bait. Even when it is shaped to mimic terrestrial invertebrates, as is the mole control product Talpirid®, it may not provide the sensory clues to make it attractive food. The use of allometric equations to estimate food daily food intake rate introduces additional uncertainty. The food intake rate was estimated from the body weights of the animals using allometric equations. How well the generic allometric equations used predicts the specific food intake rate of the assessed species is uncertainty. For example, the relationship for the AW was based on an equation developed for insectivorous, whereas the AW consumes a wide variety of vertebrate prey in addition to terrestrial invertebrates.

The assessment of secondary exposure to the AW involves additional uncertainties. A conservative assumption was made that the entire amount of active ingredient consumed by the prey is present in the prey animal when it is consumed by the snake. In reality, the amount of active ingredient in the prey may decrease between the time it consumes the bait by the prey and the prey is consumed by the snake as the result of elimination and detoxification. Conversely, some of the active ingredient in the prey animal will likely be metabolically transformed desmethylbromethalin, which is toxicologically more active than bromethalin. This could result in greater toxicity to total residues in the prey than would be assumed based on all of the residues being in the form of bromethalin. Finally, the amount of and rate of assimilation of bromethalin and desmethylbromethalin from the consumed prey into the snake is uncertain. Assimilation efficiency may be considerably less than the assumed 100%. Also, snakes typically digest large prey slowly over numerous days. Thus, the toxic bromethalin residues in the ingested prey may be released and assimilated into the snake slowly over numerous days. This could make the exposure less toxicity than the all-at-once oral exposure that is occurs in the acute oral toxicity studies.

The dose of bromethalin from secondary exposure is dependent on the size of the prey. The size of prey that the AW was predicted to be able to consume is uncertain. As described in Section 3.3.2, the body weight of the AW was estimated from an equation based on its length, and this body weight as then used in a second equation to predict the maximum size prey. Because the AW is a slender snake, these equations may overestimate both the body weight of this snake, and the maximum size prey which it may consume. Specifically, it is uncertain if an adult AW would be able to ingest a large Norway rat, even though these equations predict that it would.

6.2. Effects Assessment Uncertainties

6.2.1. Data Gaps

The lack of research that directly measures the secondary poisoning hazard of bromethalin in terrestrial animals increases uncertainty in the conclusions of the secondary poisoning assessment. A secondary poisoning study, in which animals are fed prey which have been allowed to feed on the bait, is needed to reduce the uncertainties in the conclusion of the secondary poisoning risk of bromethalin.

Only two studies are available that provide any information on the potential of bromethalin to cause secondary poisoning. One study (Van Lier, 1981) observed domestic dogs which were offered 600 g of ground meat obtained from rats which fed on bait containing 0.005% bromethalin for one day. A second study (Spaulding et al., 1985) was an efficacy study which was focused mainly on counting the number of rodents killed by application of bromethalin bait. Neither of these studies was adequate for drawing conclusions of the risk of secondary poisoning that registered bait products pose to the AW. First, very little descriptions of the methodologies used in these studies were published, and therefore the scientific validity of these studies is unknown. Second, the test materials used in both studies were less than that of currently-registered products. The percent AI in the test material in both studies was 0.005%, whereas concentration in many registered products of rodenticide bait is 0.01%, and the concentration in mole control bait is 0.025%. Finally, neither study was designed to identify secondary poisoning risk to reptiles. Van Lier (1981) evaluated secondary poisoning in dogs, which clearly may respond very differently than snakes. Spaulding et al. (1985) was focused on measuring mortality of rodents, and thus the carcass searching methods used may not have been effective for finding poisoned snakes. Because of these limitations, additional research on the secondary poisoning risk of bromethalin specifically to reptiles would be needed to reduce uncertainty of this assessment, or to possibly refute the conclusions of the quantitative risk assessment.

Toxicity data are completely lacking on the effects of bromethalin to terrestrial invertebrates, terrestrial plants, and aquatic plants. Because of this, indirect effects to the SMHM and the AW mediated through toxic effects on these taxa could not be assessed. Without data to complete an assessment, it must be assumed that bromethalin use potentially could cause some indirect effects as of causing adverse effects to these taxa. While this adds uncertainty to the overall risk assessment, the indirect effects mediated through effects to these taxa are considered of secondary importance, being less significant than the direct effects caused by primary dietary exposure (for the SMHM) or secondary dietary exposure (for the AW) to bromethalin bait. Any such risks of direct or indirect effects associated with effects on invertebrates and plants would only add to the risks of adverse effects already identified in this assessment, and therefore would only add additional justification to the *Likely to Adversely Affect* determinations that were reached for both species.

Finally, avian reproduction data have not been submitted for bromethalin. This increases the uncertainty of the risk assessment for the AW because birds are used as surrogates for reptiles in toxicity testing. Without avian reproduction data, chronic risks to the AW could not be assessed.

6.2.2. Extrapolation of Toxicity to Other Species

While the available toxicity data provides fairly certain information on the acute toxicity of bromethalin to small mammals and birds, extrapolation of these species to the AW is uncertain. Extrapolation to potential toxic effects to reptile and amphibian prey of the AW is also uncertain. Since no avian reproduction data have been submitted for bromethalin, chronic toxicity to birds, reptiles, and amphibians is also uncertain.

6.2.3. Sublethal Effects

When assessing acute risk, the screening risk assessment relies on the acute mortality endpoint as well as a suite of sublethal responses to the pesticide, as determined by the testing of species response to chronic exposure conditions and subsequent chronic risk assessment. Consideration of additional sublethal data in the effects determination is exercised on a case-by-case basis and only after careful consideration of the nature of the sublethal effect measured and the extent and quality of available data to support establishing a plausible relationship between the measure of effect (sublethal endpoint) and the assessment endpoints. However, the full suite of sublethal effects from valid open literature studies is considered for the characterization purposes.

Bromethalin is known to be a neurotoxin. It has been shown to cause numerous adverse behavioral and neuromuscular effects at sublethal levels. The possible impact of these sublethal effects on the survival and reproduction of the assessed species was only qualitatively characterized. To the extent to which sublethal effects are not considered in the quantitative risk assessment, the potential direct and indirect effects of bromethalin on listed species may be underestimated.

6.2.4. Potential for Aquatic Exposure

The current risk assessment for the AW and the SMHM was based solely on direct and indirect effects that may be caused by terrestrial routes of exposure. Some minor aquatic exposure may be possible from leaching of bromethalin residues from solid bait products that are not placed in bait stations or from bait placed in sewers. However, aquatic exposure from bromethalin is expected to be negligible (Section 2.10.1), and thus aquatic routes of exposure are not predicted to make significant contributions to the total exposure the SMHM or the AW. Also, indirect risk to the SMHM from potential effects on aquatic plants was assumed to be discountable. Uncertainties associated with these assumptions contribute to the uncertainty of the risk assessment.

6.2.5. Other Uncertainties

The degradation product desnitrobromethalin was observed in aerobic soil metabolism studies at concentrations as high as 43.8% of the applied material (MRID 43007901). Neither the toxicity nor the environmental fate properties of this chemical is known. Therefore, the possible additional toxicity resulting from exposure to this degradation product could not be assessed.

The secondary poisoning risk identified by the quantitative risk assessment has not been confirmed by incident reports or field studies. Unlike many of the anticoagulant rodenticides, no incidents have not been reported that conclusively associate mortality of nontarget animals with secondary exposure to bromethalin. While this lack of incidents means the predicted secondary poisoning risk is not confirmed, it does not refute the risk. Incidents of secondary poisoning of snakes may be occurring but may not be reported for various reasons. For one thing, unlike raptors and canine predators, deaths of snakes are seldom noticed, reported to authorities, and investigated. Also, it is not know how often bromethalin is included in the pesticide screens that are conducted during investigations of mortality incidents. Finally, since bromethalin is toxic at

very low levels, and occurs in bait at low concentrations, the small amount of bromethalin in the tissue of a dead animal may not be enough to detect with common analytical methods. Thus, because mortality events may not be reported, adequately investigated, and subjected to adequate analysis for bromethalin residues, the linked between bromethalin exposure and the cause of death may not be made, and mortality incidents may go unreported.

7. Risk Conclusions

In fulfilling its obligations under Section 7(a)(2) of the Endangered Species Act, the information presented in this endangered species risk assessment represents the best data currently available to assess the potential risks of bromethalin to the AW and the SMHM, and to the designated critical habitat of the AW.

Based on the best available information, the Agency makes a ***May Affect*** and a ***Likely to Adversely Affect*** determination for the use of bromethalin relative to both the AW and the SMHM. Additionally, the Agency has determined use of bromethalin has the potential to cause modification of the designated critical habitat of the AW from the use of the chemical. (Critical habitat has not been designated for the SMHM.) Given the LAA determination for the AW and the SMHM, and potential modification of designated critical habitat for the AW, a description of the baseline status and cumulative effects is provided in Attachment III.

A summary of the risk conclusions and effects determinations for the AW and the SMHM, given the uncertainties discussed in Section 6 and Attachment I, is presented in Table 7-1. A summary of the risk conclusions for the critical habitat of the AW is given in

Table 7-2. Use specific effects determinations are provided in Table 7-3.

Table 7-1. Effects Determination Summary for Effects of Bromethalin on the AW and the SMHM

Species	Effects Determination	Basis for Determination
Alameda whipsnake (*Masticophis lateralis euryxanthus*)	*May Affect* and *Likely to Adversely Affect* (LAA)	**Potential for Direct Effects**
		Risk assessment indicates use of bromethalin will likely result in direct effects to the AW from acute toxicity. Dietary exposure estimates and acute toxicity to reptiles (based on toxicity acute data for birds) result in acute RQs that exceed the LOC both primary and secondary exposure. While adverse acute effects are possible for both primary and secondary exposure, secondary exposure is considered the primary threat to this species. Data were not available to assess chronic toxicity, but since risk is predicted for acute effects, risk is also assumed for chronic effects.
		Potential for Indirect Effects
		Terrestrial prey items Risk assessment indicates use of bromethalin will likely reduce the abundance of terrestrial vertebrates which serve as prey for this species. This conclusion is based on acute RQ for birds, and acute and chronic RQs

Species	Effects Determination	Basis for Determination
		for mammals, which exceed the LOC. ***Habitat Modifications*** Risk assessment indicates use of bromethalin may adversely modify the habitat of this species by reducing the availability of small mammal burrows. This conclusion is based on acute and chronic RQs for mammals that exceed the LOC.
Salt marsh harvest mouse (*Reithrodontomys ravivertis*)	*May Affect* and *Likely to Adversely Affect* (LAA)	**Potential for Direct Effects**
		Risk assessment indicates use of bromethalin will likely result in direct effects to the SMHM from acute and chronic toxicity. Dietary exposure estimates and data on acute and chronic toxicity to small mammals result in acute RQs that exceed the LOC for primary exposure. This species is predicted to be susceptible to primary exposure through direct contact with bromethalin bait products. This contact may result in ingestion of the bait, which would likely result in acute and chronic toxic effects.
		Potential for Indirect Effects
		Habitat Modifications Risk assessment indicates use of bromethalin may adversely modify the habitat of this species by reducing the availability nest sites. This conclusion is based on acute RQs for birds and mammals, and acute and chronic RQs for mammals, that exceed the LOC. Adverse effects to birds and mammals may result in a reduction of abandoned bird and mammal nests, which are used as nest sites by this species.

Table 7-2. Effects Determination Summary for the Critical Habitat Impact Analysis

Designated Critical Habitat for:	Effects Determination	Basis for Determination
Alameda whipsnake (*Masticophis lateralis euryxanthus*)	Habitat Modification	Risk assessment indicates use of bromethalin may adversely modify the critical habitat of this species by reducing the availability of small mammal burrows. This may result in modification of PCE 3: "Lands containing rock outcrops, talus, and small mammal burrows within or adjacent to PCE 1 and or PCE 2."

Table 7-3. Use Specific Summary of the Potential for Adverse Effects by Taxa.

Uses	Potential for Effects to Identified Taxa Found in the Terrestrial Environment							
	SMHM and Small Mammals[1]		AW and Reptiles[2]		Small Birds[3]		Amphibians[4]	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
Rodent Control	Yes	Yes	Yes	Yes[5]	Yes	Yes[5]	Yes	Yes[5]
Mole Control	Yes	Yes	Yes	Yes[5]	Yes	Yes[5]	Yes	Yes[5]

1 A yes in this column indicates a potential for direct effects to the SMHM and indirect effects to the AW.
2 A yes in this column indicates the potential for direct and indirect effects to the AW.
3 A yes in this column indicates a potential for indirect effects to the SMHM and the AW.
4 A yes in this column indicates a potential for the AW.
5 Chronic toxicity data are not available to assess this species, but chronic risk may be assumed based upon the high acute risks.

Based on the conclusions of this assessment, a formal consultation with the U. S. Fish and Wildlife Service under Section 7 of the Endangered Species Act should be initiated.
When evaluating the significance of this risk assessment's direct/indirect and adverse habitat modification effects determinations, it is important to note that pesticide exposures and predicted risks to the species and its resources (*i.e.*, food and habitat) are not expected to be uniform across the action area. Bromethalin exposure and associated risks to the species and its resources are expected to rapidly decrease with increasing distance away from the sites of bait placement. Evaluation of the implication of this non-uniform distribution of risk to the species would require information and assessment techniques that are not currently available. Examples of such information and methodology required for this type of analysis would include the following:

- Enhanced information on the density and distribution of AW and SMHM within the action area and/or applicable designated critical habitat. This information would allow for quantitative extrapolation of the present risk assessment's predictions of individual effects to the proportion of the population extant within geographical areas where those effects are predicted. Furthermore, such population information would allow for a more comprehensive evaluation of the significance of potential resource impairment to individuals of the assessed species.
- Quantitative information on prey base requirements for the assessed species. While existing information provides a preliminary picture of the types of food sources utilized by the assessed species, it does not establish minimal requirements to sustain healthy individuals at varying life stages. Such information could be used to establish biologically relevant thresholds of effects on the prey base, and ultimately establish geographical limits to those effects. This information could be used together with the density data discussed above to characterize the likelihood of adverse effects to individuals.
- Information on population responses of prey base organisms to the pesticide. Currently, methodologies are limited to predicting exposures and likely levels of direct mortality, growth or reproductive impairment immediately following

exposure to the pesticide. The degree to which repeated exposure events and the inherent demographic characteristics of the prey population play into the extent to which prey resources may recover is not predictable. An enhanced understanding of long-term prey responses to pesticide exposure would allow for a more refined determination of the magnitude and duration of resource impairment, and together with the information described above, a more complete prediction of effects to individual species and potential modification to critical habitat.

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